

Withdrawn/Redacted Material

The Barack Obama Library

DOCUMENT NO.	FORM	SUBJECT/TITLE	PAGES	DATE	RESTRICTION(S)
001	Schedule	Schedule of the President	4	10/17/2023	P6/b6;
002	Email	Monday, October 17 - To: Ferial Govashiri	1	10/17/2016	P6/b6;
003	Schedule	Notional Block Schedule	10	2016	P5; P6/b6;
005	Briefing	Photo Line with Elected Officials, Administration Officials and Community Leaders - To: POTUS - From: Caitra Mahoney	2	10/16/2016	P6/b6;
009	Briefing	Congressional Supplement: Banneker High School Remarks - To: POTUS - From: Amy Rosenbaum	1	10/17/2016	P5;

COLLECTION TITLE:

Records Management, White House Office of (WHORM)

SERIES:

Subject Files - FG001-07 (Briefing Papers)

FOLDER TITLE:

1217196

FRC ID:

7995

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]
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Deed of Gift Restrictions

A. Closed by Executive Order 13526 governing access to national security information.
B. Closed by statute or by the agency which originated the document.
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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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b(9) Release would disclose geological or geophysical information concerning wells [(b)(9) of the FOIA]

Records Not Subject to FOIA

Court Sealed - The document is withheld under a court seal and is not subject to the Freedom of Information Act.

FOIA Marker

This is not a textual record. This FOIA Marker indicates that material has been removed during FOIA processing by Obama Presidential Library staff.

Records Management, White House Office of (WHORM)

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Stack:	Row:	Sect.:	Shelf:	Pos.:	FRC ID:	Location or Hollinger ID:	NARA Number:	OA Number:
M	22	14	9	3	7995	8689	6579	7404

Folder Title:

1217196

Paul Raizk

1217196

FG001-07

**Executive Office of The President
Barcode Scanning Sheet**



Collection Code:

SECLOG

**Scanned by
ORM**

Staff Name:

Document Date:

October 17, 2016

Correspondent:

Subject/Description:

BRIEFING PAPERS



Back from the OVAL

10/17/16

SCHEDULE OF THE PRESIDENT

PRIVATE

MEETING BREAKDOWN FOR PRESIDENT BARACK OBAMA

MONDAY, OCTOBER 17, 2016

WASHINGTON, DC

10:00 – 10:30 am

PRESIDENTIAL DAILY BRIEFING

Location: The Oval Office

PRESS: CLOSED

Attendees:

1. The Vice President
2. Denis McDonough
3. Susan Rice
4. Avril Haines
5. Colin Kahl
6. Director Clapper

10:45 – 10:50 am

LOAD MOTORCADE

10:50 – 11:05 am

EN ROUTE BENJAMIN BANNEKER ACADEMIC HIGH SCHOOL

Spare: Dr. Denise Whitfield, Pete Souza

LIMO: POTUS

Control: Lt. Col. Wes Spurlock

Support: Joe Paulsen, Marvin Nicholson, Luke Rosa, Caitria Mahoney,
Rachel Kopilow, Lawrence Jackson, Capt. Kyle Perry

Staff 1: Broderick Johnson, Kate Kochman, Roberto Rodriguez, Hannah
Hankins, Eric Waldo

Press: *TBD Press Wrangler*, PRESS POOL

11:05 – 11:10 am

ARRIVE BENJAMIN BANNEKER ACADEMIC HIGH SCHOOL // MOVE UP ONE FLIGHT OF STAIRS TO THE SCHOOL HALLWAY

Location: Curbside, Benjamin Banneker Academic High School
800 Euclid St NW, Washington, DC 20001

Site: Ian Rose

POTUS Hold: Room 108

Staff Hold: Locker Room

PRESS: CLOSED // WH VIDEOGRAPHER

11:10 – 11:20 am

PHOTO LINE // LOCAL LAW ENFORCEMENT PHOTOS

Location: School Hallway, Behind Gym, Benjamin Banneker Academic
High School

Site: Ian Rose

Staff: Gary Lee

Attendees: 36 attendees // 31 clicks

Setup: Standard push-and-pull photo line

PRESS: CLOSED // WH VIDEOGRAPHER (PRINCIPAL AND
INTRODUCER ONLY)



Format:

- Anita Berger, Principal of Banneker High School, is pre-set
- **YOU** greet Anita and pose for a photo; Anita departs
- **YOU** greet Ifunaya (PRO: i-foo-NA-ya) Azikiwe, **YOUR** introducer, and pose for a photo with her
- **YOU** participate in a push-and-pull photo line, shaking hands and posing for photos (26 participants, 21 clicks)
- **YOU** pose for individual clicks with local law enforcement (8 participants, 8 clicks)
- Following the last photo, **YOU** depart

Attendees manifested in event memo

11:20 – 11:25 am

MOVE TO OFF-STAGE ANNOUNCE

11:25 – 11:55 am

REMARKS AT EDUCATION EVENT

Location: Gymnasium, Benjamin Banneker Academic High School
Site: Ian Rose
Attendees: Approximately 600 attendees comprised of students, faculty and staff, White House and Department of Education invitees
Setup: **YOU** deliver remarks from a 12-foot by 12-foot fixed stage. Blue pipe-and-drape and U.S. and POTUS flags on sticks are behind **YOU**. Cut visuals include a Banneker High School banner.
Remarks: Prepared
Sound/Podium: Dual Wired Mics // Blue Goose Podium
Teleprompter: Yes
PRESS: OPEN // WH VIDEOGRAPHER

Pre-Program:

- Dasia Bando, Habeke Bekele & Kadiatou Fofana, Banneker High School Students - National Anthem
- Karim Sowell, Banneker High School Student - Pledge of Allegiance

Format:

- VOG introducers Ifunaya (PRO: i-foo-NA-ya) Azikiwe, **YOUR** introducer, to stage
- Ifunaya delivers brief remarks
- Ifunaya introduces **YOU** to stage
- **YOU** move to stage and greet Ifunaya
- **YOU** deliver remarks
- **YOU** conclude remarks and work a rope line from RIGHT to LEFT
- **YOU** depart

11:55 – 12:00 pm

LOAD MOTORCADE

12:00 – 12:15 pm

EN ROUTE THE WHITE HOUSE

Spare: Dr. Denise Whitfield, Pete Souza
LIMO: POTUS



Control: Lt. Col. Wes Spurlock
Support: Joe Paulsen, Marvin Nicholson, Luke Rosa, Caitria Mahoney,
Rachel Kopilow, Lawrence Jackson, Capt. Kyle Perry
Staff 1: Broderick Johnson, Kate Kochman, Roberto Rodriguez, Hannah
Hankins, Eric Waldo
Press: *TBD Press Wrangler*, PRESS POOL

12:15 – 12:20 pm **ARRIVE THE WHITE HOUSE**

12:30 – 1:00 pm **LUNCH**
Location: The Oval Office
PRESS: CLOSED

1:00 – 1:30 pm **POTUS TIME**
Location: The Oval Office
PRESS: CLOSED

1:30 – 2:00 pm **DESK TIME**
Location: The Oval Office
PRESS: CLOSED

2:00 – 2:30 pm



P6/b(6)

POC: Ferial Govashiri
PRESS: CLOSED

2:30 – 3:00 pm **RELEASE OF CANCER MOONSHOT REPORT WITH THE VICE
PRESIDENT // POOL SPRAY AT THE BOTTOM**

Location: The Oval Office
POC: Katie Collins
Attendees: **YOU**, Vice President Biden, Dr. Biden and 6 Senior Advisors
Setup: Oval Office Meeting
Remarks: Talking Points
PRESS: POOLED PRESS AT THE BOTTOM // WH VIDEOGRAPHER

Format:

- **YOU** greet Vice President Biden and Dr. Biden in the Oval Office
- The Vice President presents **YOU** with the Cancer Moonshot Reports
- The Vice President and the Cancer Moonshot staff brief you on the report and answer **YOUR** questions
- PRESS POOL enters the Oval Office
- POOL SPRAY begins
- **YOU** provide brief remarks.
- **YOU** turn to Vice President Biden who provides brief remarks
- PRESS POOL departs
- Vice President and Dr. Biden depart



Attendees:

1. The Vice President
2. Dr. Jill Biden
3. Steve Ricchetti
4. Kristie Canegallo
5. Don Graves, Deputy Assistant to the President and Counselor to the Vice President
6. Greg Simon, Executive Director, Cancer Moonshot Task Force
7. Dr. Lyric Jorgenson, Deputy Executive Director, Cancer Moonshot Task Force
8. Dr. Danielle Carnival, Chief of Staff and Senior Policy Director, Cancer Moonshot Task Force

3:15 – 3:45 pm



POC: Ferial Govashiri
PRESS: CLOSED

P6/b(6)

4:00 – 4:45 pm



POC: Ferial Govashiri
PRESS: CLOSED

4:55 – 5:40 pm

NATIONAL SECURITY COUNCIL DEPARTURE PHOTOS

Location: The Oval Office
POC: Meg Freshwater
Attendees: Approximately 44 clicks
PRESS: CLOSED

Attendees:

1. Suzy George, Executive Secretary and Chief of Staff of the National Security Council
2. Maren Brooks, Senior Director of the Situation Room

Departing NSC Staff and guests manifested in event memo

5:50 – 6:30 pm

WRAP UP

Location: The Oval Office
POC: Jenny Wang
PRESS: CLOSED

RON

THE WHITE HOUSE

Govashiri, Ferial EOP/WHO

Subject:

Monday, October 17

Back from the OVAL

10/17/16

10:00-10:30 am- PDB

10:45-10:50 am- Load Motorcade

10:50-11:05 am- En Route Benjamin Banneker Academic High School

11:05-11:10 am- Arrive Benjamin Banneker Academic High School //Arrival Greet//Move to TBD

11:10-11:20 am- Photo Line

11:20-11:25 am- Move to Off Stage Announce

11:25-11:55 am- Hold for Education Event

11:55-12:00 pm- Load Motorcade

12:00-12:15 pm- En Route WH

12:15-12:20 pm- Arrive WH

12:30-1:00 pm- Lunch

1:00-1:30 pm- POTUS Time

1:30-2:00 pm- Desk Time

P6/b(6)

2:00-2:30 pm-

2:30-3:00 pm- VP Cancer Moonshot Event

3:15-3:45 pm-

4:00-4:45 pm-

4:55-5:40 pm- NSC Departure Photos

5:50-6:30 pm- Wrap Up

Withdrawal Marker

Obama Presidential Library

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THE WHITE HOUSE

Washington

October 16, 2016

MEMORANDUM FOR THE PRESIDENT

FROM: JEN PSAKI
DIRECTOR OF COMMUNICATIONS

CC: DENIS MCDONOUGH
CHIEF OF STAFF

SUBJECT: Daily Message Guidance & EOP Communications Events

Education Speech

- You will deliver open-press remarks at Benjamin Banneker High School in Washington, D.C. to highlight the progress your Administration has made over the last eight years to improve education across the country.
- Sec. King, Cecilia Munoz, North Carolina State Superintendent June Atkinson and New York teacher Richard Ognibene will host a press call previewing your remarks.

The Vice President

- You will join the Vice President's meeting at the White House on the Cancer Moonshot, where he'll present his final report of the Cancer Moonshot Task Force. There will be a pool spray at the top of this meeting.
- The Vice President will tape an interview with Robert Siegel of NPR on the Cancer Moonshot.
- Dr. Biden will join the Vice President Biden deliver open-press remarks at an event in the White House South Court Auditorium on the Cancer Moonshot report to double the rate of progress in cancer prevention, diagnosis, and treatment.

The First Lady

The First Lady will host an open-press preview of the Italy State Visit.

RAPID RESPONSE/RESEARCH

- We will be assisting in research for the Italy State Visit.
- We continue to research issues surrounding the SCOTUS vacancy to assist the Communications Department.

THE WHITE HOUSE

Washington

October 16, 2016

**PHOTO LINE WITH ELECTED OFFICIALS, ADMINISTRATION OFFICIALS AND
COMMUNITY LEADERS**

DATE: October 17, 2016
LOCATION: Banneker High School
TIME: 11:10 – 11:20 AM
From: Caitria Mahoney

I. PURPOSE

YOU will meet and take 23 photos with elected officials, Administration officials, and community leaders.

II. PARTICIPANTS

Elected Officials

- Carrie Billy, President of the American Indian Higher Education Consortium
- Muriel Bowser, Mayor of Washington, D.C. (D)
- Ruben Hinojosa, U.S. Representative (D)
- Eleanor Holmes Norton, U.S. Representative (D)
- Mark Keam, Delegate of Virginia (D)
- Bobby Scott, U.S. Representative (D)

Administration Officials

- Joseph Conaty, Director of the Academic Improvement and Teacher Quality, ED
- Sujeet Rao, Senior Advisor to the Chief of Staff, ED
- Philip Rosenfelt, Deputy General Counsel for Program Service, ED
- Emma Vadehra, Chief of Staff, Department of ED

Community Leaders

- Ifunaya Azikiwe, Introducer
- Anita Berger, Principal of Banneker High School
- Elizabeth Davis, President, Washington Teachers' Union
- Arne Duncan, Former Secretary of Education
- Mark Ein, Founder, Venturehouse Group
- Muriel Howard, President, American Association of State Colleges and Universities
- Lance Jackson, Assistant Principal in Fairfax County (Lawrence Jackson's brother)
 - Beth Jackson,
 - Savannah Jackson,
 - Simon Jackson,
 - Sawyer Jackson,

P6/b(6)

- Kevin Kruger, President, NASPA
- Deepak Madala, Project Director and Navigator, Enroll Virginia
- Nathan Monell, President, National Parent Teacher Association
- Kristin Perry, Executive Director, First Five Years Fund
- Colin Powell, Former Secretary of State
 - Alma Powell, [REDACTED]
- Lena Shi, Policy Advisor, DPC (Detailee) ----- [REDACTED] P6/b(6)

III. PRESS PLAN

CLOSED Press.

IV. SEQUENCE OF EVENTS

- YOU will be directed to where the participants will be positioned.
- YOU will work a push and pull photo line, shaking hands and posing for pictures.

V. ATTACHMENTS

N/A

THE WHITE HOUSE

Washington

October 16, 2016

REMARKS AT BENJAMIN BANNEKER ACADEMIC HIGH SCHOOL

DATE: October 17, 2016
LOCATION: Banneker High School, Washington, DC
TIME: 11:25 – 11:55 AM
From: Pat Cunnane and Peter Velz

I. PURPOSE

You will visit Benjamin Banneker High School in Washington, D.C. to highlight the progress your Administration has made over the last eight years to improve education across the country, including here in Washington, D.C. where a greater share of students are being prepared for success in college and throughout their careers. The District of Columbia Public Schools (DCPS) has held to the core principles of reform your Administration has pushed for to make sure students are prepared for success in college and throughout their careers, including holding all students to college- and career-ready standards with support from its Race to the Top grant, advancing high-quality preschool for all, establishing rigorous teacher evaluation and support systems, and focusing on the need to turnaround its lowest performing schools.

You last visited Banneker High School in 2011. While Banneker was an exceptional school even then, District of Columbia Public Schools' (DCPS) graduates rates lagged well behind the rest of the nation at 53 percent in 2010-2011. As you return to Banneker on Monday, DCPS' rates have surged a remarkable 16 percentage points to 69 percent – in just over five years. This is an opportunity to underscore the importance of education to our future, highlight the reforms your Administration has made and lift up DCPS as a story of progress and Banneker as an example of excellence.

You will also announce 2014-2015 national high school graduation rates which have reached a new all-time high of 83.2 percent. The new graduation rates show improvement for all reported groups of students, including students of color, low income students, students with disabilities, and English learners (see chart attached). Black, Hispanic, and Native American students continued to narrow the gap between their graduation rates and those of their white peers.

Background: Banneker High School

Benjamin Banneker Academic High School is an application public high school, focused on rigorously preparing its students for success in college. Banneker offers rigorous coursework both Advanced Placement and International Baccalaureate courses, and an extended day program to give students the chance to participate in athletics and clubs. It

also partners with Howard University to provide 12th graders dual enrollment opportunities free of charge, so that students have an opportunity gain college credit before they complete high school. Banneker had a 100 percent graduation rate in 2015-2016, the same rate it had in 2010-2011, and has seen growth in its performance on state tests over the last year, in 2015-2016 98 percent of its students were proficient on annual assessments. Banneker serves 78 percent African American students; 100 percent of their students qualify for free and reduced priced lunch.

Introducer Bio

Ifunaya Azikiwe is a senior at Benjamin Banneker High School where she has taken advantage of the school's IB program to focus on science. Ifunaya and her parents recently completed her FAFSA application, and she is in the process of applying to pharmaceutical school. Ifunaya's parents emigrated from Nigeria for their education, and her older brother and sister are Banneker graduates. This year her sister graduated from Howard University where their family watched your commencement speech, and in middle school she met the First Lady as part of her school's Let's Move event.

II. PARTICIPANTS

- YOU
- Ifunaya (PRO: i-foo-NA-ya) Azikiwe, Introducer

III. PRESS PLAN

OPEN Press.

IV. SEQUENCE OF EVENTS

- Ifunaya (PRO: i-foo-NA-ya) Azikiwe, YOUR introducer, delivers brief remarks
- Ifunaya introduces YOU to stage
- YOU move to stage and greet Ifunaya
- YOU deliver remarks
- YOU conclude remarks and work a rope line from RIGHT to LEFT
- YOU depart

V. REMARKS

Provided under separate cover by Speechwriting

VI. ATTACHMENTS

- A. Background on DCPS and YOUR Reforms
- B. Chart Showing Progress on Graduation Rates Across Subgroups since 2010 – 2011
- C. OLA Supplement

A

BACKGROUND INFORMATION ON DCPS//YOUR REFORMS

DCPS Topline Progress/Graduation Rates: District of Columbia Public Schools (DCPS) has made significant progress in increasing graduation rates. In the 2010-2011 school year DCPS' graduation rates lagged well behind the rest of the nation at 53 percent, last month DCPS announced that its 2015-2016 graduation rate was 69 percent, a remarkable 16 percentage point increase over just five years. Many of the most significant gains have come from DCPS' large, comprehensive high schools. DCPS students have also shown real progress on assessments that compare progress between large urban school districts. The 2015 Trial Urban District Assessment (TUDA), administered by ED's Institute for Education Sciences, showed that on assessments of 4th and 8th grade DCPS students, scores were up across the board from 2009 in both reading and math. From 2013 to 2015, DCPS 4th graders made the largest gains in fourth grade reading in the history of the administration of the National Assessment for Educational Progress (NAEP), the nation's report card. However, DCPS still faces significant challenges, and while high school graduation rates are up, a far too high proportion of students do not gain their diploma on-time and proficiency rates on annual assessments are still very low for many of the district's comprehensive high schools.

Advancing our Signature Reforms, Beginning Race to the Top: Bolstered by \$75 million in Race to the Top funds, DCPS, the Office of the State Superintendent for Education for D.C., and 29 public charter organizations came together to: support the implementation of college- and career-ready standards; build a stronger pipeline for effective teachers and leaders; and create conditions to support and attract educators to DC's persistently low-achieving schools. A significant part of these efforts has been the implementation of the District's teacher evaluation and support system, which combines regular high-level evaluation with performance-based bonuses or salary increases. A 2013 study determined that this system, first introduced in 2009, has been a success, creating "meaningful" improvements in teacher performance in the district. Before this compensation reform, it took teachers a minimum of 21 years to reach the maximum salary; now, it only takes eight years. Further, DC has supported teacher residency programs, resulting in the placement of 137 teachers in hard-to-staff areas like early childhood, math, and science. These reforms have been critical to the District's sustained progress over the last several years, including increased graduation rates and student achievement.

Universal Access to High-Quality Preschool: DCPS significantly expanded its investments to preschool in 2008, following the passage of Pre-K Enhancement and Expansion Act of 2008, which allowed for the provision of high-quality, universally accessible preschool to all of the district's preschool-aged children. Key provisions in the law included formula-based funding for preschool and applying the high-quality performance standards of Head Start across all of the District's preschool settings to allow for the braiding of Head Start dollars with DCPS preschool dollars. Following the passage of that legislation, enrollment of four-year olds in DC preschools went from 68 percent to 90 percent. In the 2013-2014 school year, 99 percent of all four year olds and nearly 70 percent of all three-year olds residing in the District attended state-supported preschool. DC has the highest percentages of three- and four-year olds enrolled in high-quality preschool of all the U.S. States and territories.

My Brother's Keeper (MBK): Reducing the disproportionate impact of exclusionary school discipline practices has been a core part of MBK's work to improve life outcomes for all children, including boys and young men of color. In December 2014, the Departments of Health & Human Services and Education released the first federal policy statement discouraging the use of suspension and expulsion in preschool settings. The Department of Education's Civil Rights Data Collection, which aggregates school-level information from every district and state in the country, shows that black children are nearly four times as likely as white children to receive a suspension or expulsion in preschool. Universal access to preschool classrooms in DC and the evidence of negative impacts of expulsions and suspensions on the developmental of young children spurred the District to take action that protects the city's youngest learners. In January of 2015, The Pre-K Student Discipline Amendment Act of 2015 was introduced, and a few months later, it was passed. Beginning in school year 2015-2016, the law prohibits, with few exceptions, the suspension or expulsion of any preschool aged student from a publicly funded pre-K program.

B

PROGRESS ON GRADUATION RATES ACROSS SUBGROUPS

National Graduation Rates by Subgroup of Students					
	<i>2010-2011</i>	<i>2011-2012</i>	<i>2012-2013</i>	<i>2013-2014</i>	<i>2014-2015</i>
Total	79	80	81.4	82.3	83.2
American Indian/Alaska Native	65	67	69.7	69.6	71.6
Asian/Pacific Islander	87	88	88.7	89.4	90.2
Hispanic	71	73	75.2	76.3	77.8
Black	67	69	70.7	72.5	74.6
White	84	86	86.6	87.2	87.6
Low Income Students	70	72	73.3	74.6	76.1
English Learners	57	59	61.1	62.6	65.1
Students with Disabilities	59	61	61.9	63.1	64.6

Note: In 2010-2011, all states and districts began reporting the Adjusted Cohort Graduation Rate (ACGR) a new graduation rate measure, which is more accurate than other measures states previously used (e.g. the percentage of entering 12th graders who earn a diploma on-time). To calculate the ACGR, states identify the “cohort” of first-time 9th graders in a particular school year, and adjust this number by adding any students who transfer into the cohort after 9th grade and subtracting any students who transfer out, emigrate to another country, or pass away. The ACGR is the percentage of the students in this cohort who graduate within four years.

C

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October 16, 2016

RELEASE OF CANCER MOONSHOT REPORT WITH THE VICE PRESIDENT

DATE: October 17, 2016
LOCATION: Oval Office
TIME: 2:30 – 3:00 PM
FROM: Greg Simon, Executive Director, Cancer Moonshot Task Force

I. PURPOSE

In a meeting in the Oval Office, Vice President and Dr. Biden will present YOU with the Cancer Moonshot Report. The report includes the Vice President's vision for transforming the cancer research and care ecosystem, the activities and recommendations of the Cancer Moonshot Task Force for dramatically accelerating progress, and the Cancer Moonshot Blue Ribbon Panel's priority areas of scientific opportunity.

Accompanying these findings and recommendations, the Cancer Moonshot is announcing a new set of Federal actions and collaborative partnerships in the private, academic, advocacy, and philanthropic sectors, among others, that focus on progress directly related to the patient. Building on the commitments announced at the June 29th Cancer Moonshot Summit, these new actions have a directed focus on putting patients' needs first, by addressing both the social and systematic barriers to holistic, high quality oncology care and access for every cancer patient.

As YOU know, during YOUR 2016 State of the Union Address, YOU called on Vice President Biden to lead a new, national Cancer Moonshot focused on making a decade of progress in preventing, diagnosing, and treating cancer in 5 years, ultimately striving to end cancer as we know it. YOU issued a Presidential Memorandum to establish the Cancer Moonshot Task Force, which was directed to unite the Federal government in achieving the Moonshot's mission through a focused effort to leverage Federal investments, targeted incentives, private sector efforts, and patient initiatives, among other mechanisms. The Memorandum also directed the National Cancer Institute (NCI) at the National Institutes of Health (NIH) to form the Cancer Moonshot Blue Ribbon Panel (BRP) to bring together experts in a variety of disciplines to identify key areas of science for new investment at NCI.

After travelling the country and the world listening to experts across the oncology research and care spectrum, Vice President Biden identified areas of focus for the Cancer Moonshot based on barriers to progress and opportunities for improving patient outcomes, and announced a first wave of accomplishments at the Cancer Moonshot Summit on June 29th at Howard University.

By the end of YOUR Administration, the Cancer Moonshot will have completed the launch of a series of coordinated efforts that incentivize bold, creative, and disruptive approaches to conducting cancer research, that promote prevention and early screening, and that address critical needs in cancer care. These efforts leverage talent and expertise across disciplines, sectors, and borders and ensure rapid dissemination of information to the broader cancer research and care community to accelerate progress.

Ultimately, these efforts capitalize and build upon the progress made from the beginning of this Administration to accelerate biomedical research, leverage data and technology, and improve the nation's access to first-rate, affordable health care.

II. PARTICIPANTS

- Vice President Joe Biden
- Dr. Jill Biden
- Steve Ricchetti, Assistant to the President and Chief of Staff to the Vice President
- Kristie Canegallo, Assistant to the President and Deputy Chief of Staff of Implementation
- Don Graves, Deputy Assistant to the President and Counselor to the Vice President
- Greg Simon, Executive Director, Cancer Moonshot Task Force
- Dr. Lyric Jorgenson, Deputy Executive Director, Cancer Moonshot Task Force
- Dr. Danielle Carnival, Chief of Staff and Senior Policy Director, Cancer Moonshot Task Force

III. PRESS PLAN

POOLED Press. WH Videographer will cover the meeting and the spray.

IV. SEQUENCE OF EVENTS

- YOU greet Vice President Biden and Dr. Biden in the Oval Office.
- The Vice President presents YOU with the Cancer Moonshot Reports
- The Vice President and the Cancer Moonshot staff brief you on the report and answer YOUR questions.
- POOL enters the Oval Office.
- YOU provide brief remarks.
- YOU turn to Vice President Biden who provides brief remarks.
- POOL Departs.
- Vice President and Dr. Biden depart.

V. REMARKS

Pool spray talking points will be provided under separate cover.

VI. ATTACHMENTS

- A. Vice President's Report to YOU
- B. Cancer Moonshot Task Force Report
- C. Cancer Moonshot Blue Ribbon Panel Report – At A Glance

A



CANCER MOONSHOT

Report to the President
From the Vice President

October 17, 2016







October 17, 2016

Dear Mr. President:

As we walked out into the Rose Garden nearly a year ago and I announced that I would not run for president, you turned to Jill and me and asked if I had any regrets. I replied with the only one I had – that I wouldn't be the president who presided over the end of cancer as we know it. I said it because I believe it's possible.

As every family facing cancer does, Jill and I and our family learned as much as we could about the cancer our Beau fought from the diagnosis to the very end. We had access to the world's best nurses, physicians, and researchers. And the more time we spent with them, the more we understood that even if we couldn't save our son, the science, medicine, and technology are progressing faster than ever to save countless other sons and daughters. There's a recognition that the cancer system of the 20th Century must be reimagined for the 21st Century to be as powerful and interconnected as our new advances and match the real sense that we're at an inflection point in this fight.

A few months later during your State of the Union Address, to my surprise and with my gratitude, you asked me to lead a new "Cancer Moonshot" to inject a sense of urgency to seize this moment. You followed up with a Presidential Memorandum putting me in charge of a new Cancer Moonshot Task Force to unite and marshal every resource of the Federal government to achieve the Moonshot's mission – to make a decade of progress in five years in preventing, diagnosing, and treating cancer. You also created a Blue Ribbon Panel of top experts and advocates from a range of disciplines that's already identified the scientific priorities to change the many faces of cancer.

And with the charge you gave me, Jill and I also traveled around the country and the world, meeting with thousands of cancer patients and their families, physicians, researchers, philanthropists, technology leaders, heads of states, and even Pope Francis. We sought to better understand and break down the silos and stovepipes that prevent sharing of information and impede advances in cancer research and treatment, while building a focused and coordinated effort at home and abroad.

This report to you outlines what we've accomplished in year one and lays out the roadmap for the continuation of a five-year plan. And it's also a report to the American people, sharing the story of the spirit of discovery that defines this country and that gives me every confidence that we can do this.

As you know very personally, cancer touches us all in some way and at some point. Everywhere I go, people share their stories of heartbreak and hope. And every day, I'm reminded the Cancer Moonshot is bigger than just a single person. It carries the hopes



and dreams of millions of people who are praying that we succeed, praying for hope, praying for time—not someday, but now.

It's all of us coming together for the loved ones we've lost and the ones we can save.

Joe



Launching the Cancer Moonshot

The mission of this Cancer Moonshot is not to start another war on cancer, but to win the one President Nixon declared in 1971. At that time, we didn't have the army organized, didn't have the military intelligence to know the enemy well, and therefore didn't have the comprehensive strategy needed to launch a successful attack – now we do. Because of the progress over the last 45 years we have an army of researchers and oncologists, the powerful technologies and weapons, and immense public support and commitment to action.

Immediately following the launch of the Cancer Moonshot, I engaged in an extensive “listening tour”, meeting with patients and their families, physicians, researchers, and other experts to gain an even better understanding of what challenges impede advances in cancer research and treatment, and what opportunities could be realized with a focused and coordinated effort. I visited many of the major nerve centers in the fight against cancer to gain as much information as I possibly could in order to meet our goal and sense of urgency.

I learned there is consensus that in the cancer fight, we have reached an inflection point, and there is good reason to have hope. Let me explain what I mean by that:

- There is more collaboration across research disciplines than ever before, and this is needed to solve the complexity of a challenge like cancer. Five years ago, oncologists weren't routinely working closely with immunologists, virologists, geneticists, chemical engineers, and others – now they are.
- Because of technological advances, researchers are now able to analyze cancer genes and proteins, along with other genes in the body, putting us closer than ever before to understanding what causes cancer and how to attack a particular cancer.
- Using this improved understanding of cancer biology, we can now target and treat cancer cells with therapies that boost the immune system, that use low doses and new forms of radiation, and more targeted chemotherapy. Many of these new treatments are effective at killing cancer cells while doing less damage to healthy cells, advances could eventually transform many types of cancer that are currently hard to treat such as liver cancer, brain cancer, and pancreatic cancer into chronic, manageable diseases.
- Everywhere I travelled, I was told that data are key, and we have an unprecedented amount and diversity of data being generated daily through genomics, family history records, lifestyle measurements, and treatment

outcomes; with this data we can find new patterns of causes, earlier signs of cancer, and successful treatments of cancer.

- We now have the capability to realize the promise of all of these data because of advances in super computing power. Researchers can analyze enormously complex and large amounts of data to find answers we couldn't just five years ago.
- And we have more Americans than ever before covered by health insurance, through the Affordable Care Act (ACA). As a result of the ACA, a diagnosis of cancer doesn't mean you lose your insurance if you change plans because you have a pre-existing condition. And it means more Americans can take advantage of prevention tools and early screening measures leading to earlier detection of cancer that results, in many cases, in better outcomes.

Challenges and Opportunities

While there is great promise and reason to be optimistic, we must meet this opportunity with action. There are remaining barriers that must be addressed as part of the Cancer Moonshot. From my interactions it was increasingly clear, that there is a lack of coordination among efforts, a failure to share information both rapidly and effectively, and an antiquated culture of research and funding. Specific barriers include:

- Incentive structures that encourage and reward individual success rather than cross-discipline and cross-sector collaboration, making it even harder to pursue team science which can lead to new answers and new solutions.
- Poor retention and recruitment in cancer clinical research trials, and insufficient dissemination of successful strategies for engaging participants as partners in research. These inefficiencies can lead to costly hurdles in conducting successful trials and unacceptable delays in getting new treatments to patients.
- A lack of open access and rapid sharing of research data and results allowing researchers to build on each other's successes – and failures – to make new discoveries faster.
- Hurdles surrounding the sharing of medical records that offer no additional level of protections for patients.
- Insufficient collaboration around, and utilization of, technological capabilities to harness the vast amounts of data within our electronic health records to improve cancer prevention, diagnosis, treatment, and care.
- Slow dissemination of "cancer center knowledge" – new discoveries, new diagnostics and screening measures, new clinical trials, and new treatments -

equitably throughout the population, especially in community practices across the United States.

But I am convinced these barriers are not insurmountable. And, through the work of this Administration and the efforts of Cancer Moonshot, we are already making progress.

Progress on the Cancer Moonshot

Cancer Moonshot Task Force

I have been amazed and impressed by the response to this new effort to end cancer as we as know it, this Cancer Moonshot, with individuals and organizations, agencies, and nations stepping up to take on these challenges.

Mr. President, under the Cancer Moonshot Task Force you created, my first order of business was to infuse a new sense of urgency within the Federal government, to bring together department and agency leaders to unite their focus in removing unnecessary barriers and launching new programs and collaborations. I am pleased to announce the progress we have made in this short time.

For instance:

To share research results and data faster, NIH launched a new partnership, to bring together drug companies, major cancer research centers, foundations, and philanthropies to collaborate on early stage research – i.e. the basic biology of cancer – and to share all of the data with everyone. So instead of 20 companies each studying the same thing and not sharing the results, they'll be able to see each other's findings and build upon the results more quickly. The drug companies have realized this is in their interest and more are signing up.

To encourage a greater sense of collaboration, NCI, in June, launched a Drug Formulary – a new public-private partnership with 20-30 pharmaceutical and biotechnology companies that allow researchers to more easily license and test their existing drugs for new combinations that could be effective against different types of cancer. Trials using combination therapies (therapies using more than one drug), which potentially improve the likelihood of curing a particular cancer, can now be streamlined to move more quickly.

To support innovation, the U.S. Patent and Trademark Office (USPTO) launched a free and accelerated pilot program that aims to cut in half the time it takes to review patent

applications in select fields of cancer therapy, from an average of about two years to less than 12 months. The USPTO also opened up their application data and challenged innovators to develop new ways to study gaps and great areas of promise in cancer research based on patent filings.

To apply 21st century technology to biological questions, the U.S. Department of Veteran's Affairs (VA) and the Department of Energy (DOE) have partnered to apply the most powerful computational assets at the DOE's National Labs to over half a million veterans' records from one of the world's largest research cohorts – the Million Veteran Program – a cornerstone of your Precision Medicine Initiative. The collaboration is poised to drive new understanding of cancer and new patterns in effective treatments as part of the Cancer Moonshot.

To streamline and coordinate review of cancer products, the U.S. Food and Drug Administration (FDA) created an Oncology Center of Excellence (OCE) to maximize the availability of oncology expertise and review on cancer-related applications. The OCE unites cancer product regulatory review to enhance coordination and leverage the combined skills and clinical expertise across FDA centers to accelerate bringing new, safe therapies to market.

To implement successful prevention measures, the Centers for Disease Control and Prevention (CDC) is advancing its efforts to promote cancer vaccines as a safe and effective strategy for combatting various types of cancers. This centers on working to increase HPV vaccination rates by raising awareness about the importance of vaccinating males and females ages 11-12, and maximizing access to and opportunities for vaccination.

And to increase the ability for patients to participate in clinical research, the NCI has adopted a new “dashboard” that makes it easier for patients and doctors to search for clinical trials. This dashboard was created by the Presidential Innovation Fellows in partnership with the NCI to maximize the user experience when they go to www.trials.cancer.gov.

As part of this work, the Task Force identified ways in which the Cancer Moonshot could build on this Administrations related efforts, including our push to increase biomedical research funding and the launch of programs like the Brain Research through Advancing Innovative Neurotechnologies (BRAIN) Initiative and the Precision Medicine Initiative (PMI).

Private Sector Engagement and Action

But, Mr. President, we all know the Federal government cannot do this alone. As part of igniting the Cancer Moonshot national conversation and call to action, on June 29, 2016, I brought together nearly 400 cancer researchers, oncologists, nurses, patients, their families, advocates and others in Washington, D.C. for a Cancer Moonshot Summit. Over 7,000 more convened at hospitals, community care centers, businesses, and in family rooms at more than 300 local summits across all 50 states, Puerto Rico, and Guam.

The goal of this Summit was to ignite a national – and even international – conversation to fundamentally change the trajectory of progress in cancer prevention, diagnosis, treatment, and care to make a decade’s worth of progress in half the time. Including the Summit and the release of this report, we will have announced 54 new private sector actions and collaborations, in addition to new Federal efforts, to make progress on Cancer Moonshot goals.

Responses to our call to action have emerged from across the country, with organizations committing to make a difference as part of the Cancer Moonshot—from the American Cancer Society setting the goal of doubling their research investment over the next five years, to the Alex’s Lemonade Stand Foundation doubling its investment in childhood cancer research projects and family services over the next five years, to ride-sharing services like Uber and Lyft offering reliable and affordable travel to treatments and appointments for patients who need it.

Others have stepped up, as well, for example, Deloitte’s “Conquering Cancer” XPRIZE focused on simplified early detection technologies was certified by XPRIZE as ‘ready for launch’ at the Visioneers 2016 Summit. This competition will bring new minds and teams together to develop innovative solutions for early detection. And, Cancer Support Community (CSC), a world-wide network of community-based and online patient support, launched the Frankly Speaking About Cancer Clinical Trials program, to reach at least half a million patients with an education series devoted to dispelling common myths and building awareness among patients and caregivers about the importance of clinical trials.

And in communities across the country, local governments and cancer centers are taking up the challenge. For example, the MedStar Washington Hospital Center, Washington Cancer Institute, launched a “Colon Cancer Prevention in the Neighborhood” Program to take place over the next year. The goal is to deploy a team of healthcare professionals to work with neighborhoods in Washington, D.C. to build community-based partnerships to deliver colon cancer education, perform risk assessments, and distribute colon cancer tests to return for free testing for over 1,400 residents. And Mercy Hospital has answered the call by doubling the number of free mammograms, diagnostic procedures and breast health education programs to the uninsured and underinsured women in the Oklahoma City community. Through

Project Early Detection, more than 1,100 women will be offered access to breast health care.

The Cancer Moonshot has spurred new private partnerships and collaborations. For example:

- Representatives from government, academic, pharmaceutical and diagnostic companies have agreed to accelerate the development of an open database for blood profiling diagnostic technologies for patient benefit.
- Earlier this year, I was in Chicago for the launch of the NCI's Genomic Data Commons – a platform built by the University of Chicago for the NCI and also part of your Precision Medicine Initiative. With this new national resource, researchers can freely access raw genomic and clinical data for more than 32,000 patients, with patient privacy and data security safeguards in place, and more records to follow. Increasing the pool of researchers who can access data – and decreasing the time it takes for them to review and find new patterns in that data – is critical to speeding up the development of lifesaving treatments for patients. And we know that people are finding this resource valuable, with more than 5 million users and more than 50 million data downloads worldwide since June.
- Because of the Cancer Moonshot call for greater prevention efforts, there's now a collaboration between George Washington University and the Case Comprehensive Cancer Center focused specifically on tobacco cessation and cancer prevention and screenings. Washington, D.C. and Cleveland have higher than the national average smoking rates. This new program uses social media and digital monitoring technologies to help people adopt healthier life styles.
- IBM, the U.S. Department of Defense (DoD, Walter Reed Murtha Cancer Center) and VA have launched a public-private partnership to help doctors scale access to precision medicine for 10,000 American Veterans with cancer over the next two years. VA cancer patients will have DNA sequenced at the Murtha Cancer Center, and IBM will provide Watson for Genomics, which has been trained for genomic analysis, to VA doctors to help them identify the likely cancer-causing mutations and treatment options that target those specific mutations – a data-intensive process that has been time consuming and difficult to scale in the past.

Earlier this year, I was asked by the Vatican to keynote its conference on regenerative medicine and talk about the Cancer Moonshot. At the conference, I outlined five pillars for an international commitment to change the culture of our global fight against cancer.

- 1) Increase global focus on cancer prevention, and treatment access and affordability.
- 2) Raise the international response to cancer with the same urgency we bring to infectious disease threats.
- 3) Increase research and patient data sharing – among researchers, institutions, foundations, and nations.
- 4) Support international standardization of data and bio-repositories, so records can be easily shared and compared with data from medical centers across the world.
- 5) Increase worldwide government investment in cancer research.

During the United Nations General Assembly meeting in September, I announced three major steps that go to the heart of these pillars and demonstrate the progress we have made this year.

First, the United States executed ten new Memoranda of Understanding (MOUs) and commitments to nine nations that will support greater international cancer research and care. For example, seven of these MOUs – with institutions in Canada, China, Germany, Switzerland, Taiwan, Japan, and the Republic of Korea – focus on the emerging field of proteogenomics, which studies the relationship between genes and proteins and, in this case, their role in cancer.

Second, we announced NCI investment in the creation of regional hubs to help reduce disparities in cancer research – in parts of the world that are under-resourced to support research and programs to deliver better cancer prevention, diagnosis, and care.

Third, the U.S. Department of State has strengthened U.S. bilateral science and technology engagements – engagements the United States has with more than 70 countries – to support the Cancer Moonshot and these international guideposts.

Cancer Moonshot the Road Ahead: Strategic Plan

I am enthusiastic about what can be accomplished when we are united in this fight. We have demonstrated what can be achieved and what is possible. We must continue to support the charge, as so much more is left to do to truly improve patient outcomes. Moving forward, we must focus our efforts in a few strategic areas.

Realign the Incentives in the Research System

Mr. President, one of the most common things I hear is that we need to realign incentives in our cancer research enterprise. This is a message I took up when I addressed 5,000 of our nation's top cancer researchers at a major conference in New Orleans.

Our cancer system as we know it was established in 1971, when President Nixon signed the National Cancer Act, initiating the first National Cancer Program, the President's Cancer Panel and the National Cancer Advisory Board. But it is time to re-imagine a cancer enterprise for the 21st century.

The central role of government in funding cancer research requires us to reinvent our approach periodically to match the times --- and the opportunity, and that time is now. System reform and the establishment of new incentives are essential aspects of the Cancer Moonshot to ensure that scientific progress can accelerate at the pace needed to achieve our goal. I am working across the Federal government and with the private, academic, and philanthropic sectors to identify areas in which system change could lead to meaningful and sustained impact for patients. Areas for further action include:

- Implementing strategies for spurring innovative cancer research, particularly those supported by the NCI by:
 - Creating new funding mechanisms for supporting high-risk/high-reward research;
 - Implementing pilot programs to accelerate receipt, review, and funding of meritorious research proposals;
 - Incentivizing public access to publications at the time of publication; and
 - Reforming and revitalizing the NCI intramural research program (its cadre of Federal scientists) as a center of excellence for addressing emerging scientific opportunities or grand challenges in public health, including cancer.

Enhance Prevention and Screening Efforts

By some estimates, at least 50 percent of cancers can be prevented. Prevention falls into three major categories of action: (1) personal actions of an individual, such as living a healthy lifestyle and avoiding cancer risk behaviors, such as smoking; (2) responsibilities of a government, such as reducing carcinogens in the air, ensuring the availability of clean drinking water, and protecting its citizens from known toxins; and (3) technology and medical advances that enable us to prevent and detect cancer earlier. While there is progress to make across all of these areas, there is great potential for new breakthroughs in the last category. There is new hope, as emerging technologies are paving the way for new non-invasive and mobile imaging techniques and new genetic "markers" to identify those at risk for developing cancer long before the cancer progresses.

We must continue to invest in research to understand cancer prevention and in new, effective, methods to reach individuals and communities with prevention tools and education, recommended vaccinations, and early screening.

Engage Patients as Partners in Research

While the challenges around patient data in the healthcare system are not trivial to overcome, there are some known steps that we must take. Ultimately, we have to build a network—centered on the patient—that makes data accessible, shareable, and meaningful. And we must advance a modern, interoperable electronic health ecosystem, with patient access and sharing capabilities between clinical care providers and research. This Administration has made critical improvements in this area, such as clarifying patients' rights to access their health information and overseeing the adoption of electronic health records in clinical care. But there is more to do.

To realize this, we should provide all patients the ability to easily access, reconcile, and share their health information in ways that work for them, so that they can make informed decisions about their healthcare. These steps will also enable patients, especially those who have multiple providers, improved care coordination and delivery since they would be able to bring their records with them—or have them sent in advance—as they move between doctors and practices. Importantly, this system must respect and protect patients' preferences for privacy, and allow them to use their data as they choose.

For example, additional steps could include:

- Coordinating pilots with providers and electronic health record vendors to make it easier for cancer patients to share copies of their records for their own care coordination or data donation to research;
- Ensuring individuals understand their rights to direct their data where they want it to go, helping put them in control of their health and care;
- Creating the ability for patients to have all of their information in one accessible location. At the patient's direction, clinical information would automatically be sent to this location and patients would be able to easily share their data from the location with providers, family or researchers.
- Implementing a rapid standards adoption process for medical data similar to the standards used for clinical data; and
- Promoting the adoption of interoperable electronic health system through effective incentives and contracting requirements.

Expand Access to Care

We must ensure that advances in research and care benefit all segments of society and that our commitment to diversity in cancer clinical trials reflects the critical importance of ensuring that access is equitable. We must provide better support to patients so that gains in precision oncology are matched by improvements in individualized treatment.

And we must support the delivery of quality oncology care to every cancer patient regardless of socioeconomic factors, rarity of illness, age, or geographic limitations in healthcare access.

To realize this we could:

- Engage more communities in cancer research to develop better genomic, environmental and treatment response data about cancer in underserved and underrepresented populations. This includes, exploring ways to address the challenges that limit minority participation in clinical research (e.g., social determinants of health), and ensure that historically underrepresented communities are involved in the planning, design, and implementation of clinical trials.
- Allocate Federal and private funds to support the frontline efforts of community clinics in increasing health literacy among all populations, involving community groups to promote the value of prevention, early screening, and cancer clinical trial participation, and optimizing medical interactions to raise awareness and recruit potential participants.
- Promote best practices for both cancer centers and community practices that effectively and sustainably address cancer disparities.
- Identify pathways for disseminating clinical advances to community oncologists and their patients.
- Endorse public-private partnerships that innovate drug development for rare and pediatric cancers.
- Support research in cancer survivorship, and identifying best practices in clinical management of the patient in remission.

Create New Financial Models to Improve Development of and Access to New Therapies

We must create new financial mechanisms to leverage private investment to advance new cancer prevention methods, diagnostics, and therapies. We must ensure that insurance coverage decisions are rooted in data, including medical efficacy, clinical effectiveness, and ultimately health outcomes. We must improve pathways and opportunities for medically uninsured and underinsured cancer patients to obtain preventive measures and life-saving treatments. And we must create incentives through legislative, regulatory, and reimbursement venues to enhance cooperation and collaboration across the industry as early as possible in the development cycle, especially in the development of new products and treatments for rare and pediatric cancers.

We must address the escalating costs of cancer care. Lifesaving drugs are expensive to develop and create great value to individuals and society. It is important that we continue to incentivize investment in this area, and that the lifecycle of drug development can be sustained. But price increases without any market justification have become the norm not the exception in the pharmaceutical industry and pose a problem for payers and patients. Often price increases benefit the middlemen while disadvantaging patients. Co-pays are often more expensive for the most efficacious drugs than for less effective drugs, further distorting the system. We need to have a national conversation, including biopharmaceutical companies, insurers, pharmacy benefit managers, Congress and patient advocacy groups, about drug pricing to ensure that high-quality treatment is financially accessible to all patients, including vulnerable and medically-underserved populations and that we have a more rational system to distribute the costs of new medications.

To realize this, we could:

- Convene finance and philanthropic leaders to spur the development of additional private investment models in alignment with the Cancer Moonshot.
- Explore options for the Federal government to establish a bond or fund to leverage taxpayer dollars to bring compounds and devices across the “valley of death” between foundational research and applications to healthcare delivery.
- Have a national conversation, including biopharmaceutical companies, Congress and patient advocacy groups, about drug pricing to ensure that high-quality treatment is financially accessible to all patients, including vulnerable and medically-underserved populations.

Concluding Thoughts

Mr. President, earlier this year I spoke at Rice University, nearly fifty years to the day from when President Kennedy spoke about the Nation’s first moonshot, when he said,

*“We choose to go to the moon in this decade and do the other things,
not because they are easy,
but because they are hard,
because that goal will serve to organize and measure the best of our energies and skills,
because that challenge is one that we are willing to accept,
one we are unwilling to postpone, and
one which we intend to win, and the others, too.”*

That’s where we are today in our Cancer Moonshot. While there is only one moon, there are more than 200 distinct kinds of cancer – not all susceptible to the same detection strategy or treatment, but each requiring all of us to be unwilling to postpone.

There are thousands of brilliant researchers spending nights and weekends in their labs looking for the next breakthrough. Countless patients full of courage, hoping they can return to their lives and their families, or asking for just three more months to walk a daughter down the aisle. Brave family members starting foundations, not just to remember, but to honor their husband, wife, brother, sister, son, or daughter. Companies and entrepreneurs developing cures and technologies the right way for the right reason. Everyone from philanthropists pouring their own money into the fight to the little girl and her lemonade stand doing her part to help her classmate. And it's the Congress stepping up for massive increases in funding for cancer research and care.

The Cancer Moonshot is a movement that lives in communities across the United States and the world — and it will live long after we leave office. Mr. President, we can't afford for it not to, because the need is too great and the promise even greater.

Like President Kennedy challenged the nation before, let this Cancer Moonshot challenge all of us to think anew about what is possible and end cancer as we know it.

It won't be easy.

But we can do this.

We can give more time.

We can give more hope.

Not someday — but now.

B



CANCER MOONSHOT

Report of the Cancer Moonshot Task Force

October 17, 2016







Executive Summary

In his 2016 State of the Union Address, President Obama called on Vice President Biden to lead a new, national “Cancer Moonshot” to dramatically accelerate efforts to prevent, diagnose, and treat cancer—to achieve a decade’s worth of progress in 5 years. By leveraging decades of scientific understanding from the study and care of cancer, creating and aggregating immensely powerful datasets, and developing unprecedented science and technological capabilities, we as a Nation are positioned to end cancer as we know it.

In pursuit of this mission, President Obama established the Cancer Moonshot Task Force charged with leveraging federal investments, targeted incentives, private sector efforts, patient engagement initiatives, and more, to support cancer research and enable progress in prevention, diagnosis, and treatment. Never before have so many government agencies come together—committing their leadership and uniting their focus—to tackle the challenges along the spectrum of cancer research and care to improve outcomes for patients.

Private sector collaborations and other efforts spurred by the Vice President’s leadership, in addition to his vision for igniting new innovation within the biomedical research enterprise, are outlined in an accompanying executive report. A Blue Ribbon Panel was also formed, which recommended areas of scientific opportunity to complement the Task Force’s activities. These collective efforts are not intended to replace existing cancer programs, initiatives, and policies already underway, but rather are focused on areas in which a coordinated effort can dramatically accelerate the pace of progress in the fight against cancer.

This report presents the Task Force’s Implementation Plans for accelerating progress, including actions launched under the Cancer Moonshot this year, as well as longer-term plans for continuing momentum into the future. In brief, the organizing framework and recommendations are as follows:

Strategic Goal 1 – Catalyze New Scientific Breakthroughs

We are witnessing widespread and unprecedented optimism that we are on the verge of pivotal advances in oncology research. Under Strategic Goal 1, the Task Force is advancing the pace of scientific discovery by:

- Fostering interdisciplinary approaches for elucidating the biological mechanisms underlying cancer onset and treatment;
- Aligning research and care as a seamless and iterative process; and
- Maximizing the collection and research use of longitudinal data and biospecimens.

Strategic Goal 2 – Unleash the Power of Data

Today researchers are working with an unprecedented amount of data, in part due to the explosion of genomic information, increasing use of electronic health records, and large datasets of clinical, environmental, and public health information. Under Strategic Goal 2, the Task Force is maximizing access to and usability of these data to enhance, improve, and inform the journey of every cancer patient by:



- Enabling a seamless data environment for clinical and research data through shared policies and technologies;
- Unlocking scientific advances through open publication and storage platforms and next-generation computer architectures; and
- Developing a scientific workforce capable of using the open and connected data environment.

Strategic Goal 3 – Accelerate Bringing New Therapies to Patients

The process by which lifesaving products are moved into clinics is poised for transformation, especially given the access to new and innovative strategies for moving an idea from “bench to bedside.” Under Strategic Goal 3, the Task Force is accelerating this transformation by:

- Finding efficiencies in the regulatory review and licensing processes;
- Enhancing data sharing across sectors and incentivizing pre-competitive collaborations; and
- Strengthening the oncology clinical research enterprise.

Strategic Goal 4 – Strengthen Prevention and Diagnosis

As we gain an increasing understanding of the causes of cancer, the public can gain cumulative benefits from the broader arsenal of tools for combatting this devastating disease. Under Strategic Goal 4, the Task Force is strengthening the Nation’s efforts around cancer prevention and diagnosis by:

- Advancing health programs, policies, and outreach to help Americans reduce their cancer risk;
- Strengthening our understanding of environmental determinants of cancer; and
- Enhancing the cancer screening continuum.

Strategic Goal 5 – Improve Patient Access and Care

The Affordable Care Act has provided a unique opportunity for opening the door to health coverage to ensure that patients have access to resources and support throughout their cancer journey. Under Strategic Goal 5, the Task Force is building on this foundation and identifying areas with the greatest potential for meaningful impacts for patients by:

- Improving efficiencies of existing programs and expanding current efforts to increase access to health care;
- Translating knowledge into workable policies to improve cancer prevention, detection, and quality of care; and
- Finding new ways of ensuring each and every patient receives quality care during treatment and survivorship.

With these goals in mind, the Task Force launched a series of activities in 2016 and developed plans to serve as a “blueprint” for future Administrations (summarized in the table below). Ultimately, through the creation of new paradigms for generating, sharing, and integrating research and clinical data to enhance patient care, the Cancer Moonshot can accelerate the delivery of effective cancer prevention strategies, diagnostics, and treatments to patients in communities around the world.



CANCER MOONSHOT IMPLEMENTATION PLAN – “AT-A-GLANCE”	
Year 1 Accomplishments and Plans	Page
Expediting researchers’ access to cancer compounds for research – National Cancer Institute (NCI) Drug Formulary	8
Strategic computing partnership between the Department of Energy (DOE) and NCI to accelerate precision oncology	8
Department of Defense (DoD) launching groundbreaking longitudinal study to revolutionize precision oncology	8
Preclinical research partnership to evaluate the potential of particle beam radiotherapy	8
Creation of an open access resource for sharing cancer data via the Genomic Data Commons	10
Harnessing big data to transform Veteran health through precision medicine	11
Tri-Agency coalition to enhance cancer care – Applied Proteogenomics Organizational Learning and Outcomes (APOLLO) consortium	12
Creation of a new program to accelerate cancer product regulatory review	16
National Institutes of Health (NIH) public-private partnership for accelerating cancer therapies	16
Forging new partnerships to catalyze new drug discovery and development	17
Patents 4 Patients: Establishment of fast-track review for cancer treatment-related patents	17
Crowdsourcing intellectual property data to guide cancer investments	17
Making clinical research trials more accessible to cancer patients	18
Strengthening and clarifying the requirements for public availability of clinical trial information	18
Promoting human papilloma virus (HPV) vaccination as cancer prevention	21
Partnership to avoid carcinogenic risks by reducing radon exposure	21
Improving patient access to medications and information	25
New federal incentives for coordinated cancer care	25
Improving cancer survivorship through art	25



CANCER MOONSHOT IMPLEMENTATION PLAN – “AT-A-GLANCE”	
Plans for Year 2 and Beyond	Page
Strengthen interactions among agencies and engage additional partners in support of multidisciplinary basic cancer research	9
Expand the implementation of mobile devices and wearable technologies for cancer diagnosis and treatment	9
Create a high-quality performance status tracking system for cancer patients during therapy and long-term follow-up	9
Rapidly analyze the molecular profile of thousands of tumors	12
Create a shared resource of linked clinical datasets	13
Improve the clinical data available for research by creating a tool that converts narrative into standardized data	13
Advance secure and scalable platforms for data and metadata management for sharing and analysis	14
Develop predictive computer algorithms to rapidly develop, test, and validate predictive preclinical models	14
Build collaborative relationships with the private sector and academia	14
Create a knowledgeable, sustainable, and agile biomedical data science workforce	15
Modernize eligibility criteria for clinical trials	18
Pilot large simple trials	18
Develop site/tissue agnostic trials and broaden indications	19
Increase the usage of common control and expansion cohort trials	19
Achieve greater interaction with pharmaceutical sponsors on international trials	19
Create a pilot program for oncology products that utilize real-world evidence	20
Strengthen the quality of intellectual property rights to invest in innovation	20
Improve HPV vaccination rates in the United States	22
Implement smoking cessation strategies across the Medicaid population	23
Screen environmental chemicals through high-throughput <i>in vitro</i> assays	23
Expand colorectal cancer screening efforts in the United States	24
Remove barriers that limit access to colorectal cancer screening	24
Identify and implement culturally and linguistically appropriate cancer education and outreach efforts	26
Require expedited coverage decisions for patients with a cancer diagnosis in the Department of Veterans Affairs system	26
Comprehensively identify cancer survivorship issues and develop solutions to improve health outcomes for cancer survivors	26
Map cancer service delivery and care across the Nation	27
Improve access to care by leveraging technology such as virtual networks	27



Cancer Moonshot Task Force

Joseph Biden, Jr

Vice President, United States

Members

Charles Bolden, Jr

Administrator, National Aeronautics and Space Administration

John Holdren, PhD

Director, White House Office of Science and Technology Policy

Sylvia Mathews Burwell

Secretary, Department of Health and Human Services

Douglas Lowy, MD

Acting Director National Cancer Institute, National Institutes of Health

Robert Califf, MD

Commissioner, Food and Drug Administration

Gina McCarthy

Administrator, Environmental Protection Agency

Ashton Carter, PhD

Secretary, Department of Defense

Robert McDonald

Secretary, Department of Veterans Affairs

Jane Chu, PhD

Chairman, National Endowment for the Arts

Ernest Moniz, PhD

Secretary, Department of Energy

Francis Collins, MD, PhD

Director, National Institutes of Health

Cecilia Muñoz

Director, White House Domestic Policy Council

France Córdova, PhD

Director, National Science Foundation

Penny Pritzker, JD

Secretary, Department of Commerce

Shaun Donovan

Director, White House Office of Management and Budget

Andrew Slavitt

Acting Administrator, Centers for Medicare & Medicaid Services

Thomas Frieden, MD, MPH

Director, Centers for Disease Control and Prevention

Thomas Vilsack, JD

Secretary, Department of Agriculture

Michael Froman, PhD, JD

Ambassador, Trade Representative

Jeffrey Zients

Director, White House National Economic Council



Cancer Moonshot Task Force Staff

Gregory Simon, JD

Executive Director

Lyric Jorgenson, PhD

Deputy Executive Director

Danielle Carnival, PhD

Chief of Staff and Senior Policy Director

Jerry Lee, PhD

Deputy Director for Cancer Research and Technologies

Lauren Leiman, MBA

Senior Director for External Partnerships

Anabella Aspiras, BSN, MPA

Director for Patient Engagement

Kara DeFrias, MEd

Director of User Experience

Lynne O'Brien, JD

Policy Analyst

Katie Collins

Policy Analyst

Kathi Hanna, MS, PhD

Science Writer

Leon Fuerth

Organizational Analyst



Table of Contents

Executive Summary.....	i
Strategic Goal 1 – Catalyze New Scientific Breakthroughs	i
Strategic Goal 2 – Unleash the Power of Data.....	i
Strategic Goal 3 – Accelerate Bringing New Therapies to Patients	ii
Strategic Goal 4 – Strengthen Prevention and Diagnosis	ii
Strategic Goal 5 – Improve Patient Access and Care	ii
Cancer Moonshot Task Force.....	v
Cancer Moonshot Task Force Staff	vi
The Opportunity: Ending Cancer as We Know It	1
The Launch: Establishment of a Cancer Moonshot Task Force	3
Charting the Course: Organizational Framework	5
Liftoff: Cancer Moonshot Implementation Plan.....	6
Strategic Goal 1 – Catalyze New Scientific Breakthroughs	6
Year 1 Accomplishments and Plans	7
Plans for Year 2 and Beyond	9
Strategic Goal 2 – Unleash the Power of Data.....	10
Year 1 Accomplishments and Plans	10
Plans for Year 2 and Beyond	12
Strategic Goal 3 – Accelerate Bringing New Therapies to Patients	16
Year 1 Accomplishments and Plans	16
Plans for Year 2 and Beyond	18
Strategic Goal 4 – Strengthen Prevention and Diagnosis	20
Year 1 Accomplishments and Plans	21
Plans for Year 2 and Beyond	22
Strategic Goal 5 – Improve Patient Access and Care	24
Year 1 Accomplishments and Plans	25
Plans for Year 2 and Beyond	26
Reaching Target: Ending Cancer as We Know It	29



The Opportunity: Ending Cancer as We Know It

"For the loved ones we've all lost, for the family we can still save, let's make America the country that cures cancer once and for all" - President Barack Obama

Recognizing this unique moment in the fight against cancer, in his 2016 State of the Union Address, President Obama called on Vice President Biden to lead a new, national "Cancer Moonshot" to dramatically accelerate efforts to prevent, diagnose, and treat cancer—to achieve a decade's worth of progress in 5 years. The progress we have made in understanding cancer in all its forms over the last several decades and the declining death rate from cancer since the early 1990s¹ have shown that a future may be possible wherein:

- all segments of society have access to prevention strategies, diagnostics, and treatments that save lives;
- there are cures for some forms of cancer and others have been turned into chronic conditions that do not diminish the quality or length of life;
- cancer researchers and doctors are collaboratively engaged in a system that accelerates knowledge and breakthroughs; and
- patients and health care professionals are partners, and patients can easily access and control their health information to use as they wish, including to further biomedical research.

While bold, the goal of the Cancer Moonshot is within our grasp. Today, society has the benefit of decades of scientific understanding and vast amounts of rich data just waiting to be transformed into solutions. We now know that cancer is hundreds of diseases, largely of our genome, and we have developed new and innovative ways of capitalizing on this knowledge. We know that our behavior and environment contribute to our likelihood of getting cancer, and we are modifying our behaviors and exposures to avoid known risks. We know that prevention and early diagnosis are key to fighting cancer, and we can build these efforts into clinical care.

Added to these advances, today, are immense science and technological capabilities that have positioned us to make a quantum leap in the fight against cancer. For instance, dramatic advances in immunotherapy—engineering our immune system to selectively target cancer cells—has shown remarkable success in treating a host of cancers.² Over just the last two decades, the cost of whole genome sequencing has fallen from in the range of millions of dollars per genome to below \$1,000.³ The increased connectedness of people through smartphones, mobile technologies, electronic health records (EHRs), and the internet allows us to reach people across communities and enables the sharing of essential information key to improving outcomes for patients with cancer. Our ability to store, mine, and analyze the vast array of data from so many sources grows every day,⁴ and the rise of data science,

¹ National Cancer Institute. The Annual Report to the Nation on the Status of Cancer, 1975-2012.

² Couzin-FJ. Cancer Immunotherapy. *Science* 20 Dec 2013, 342(6165): 1432-1433. DOI: 10.1126/science.342.6165.1432.

³ National Human Genome Research Institute. The Cost of Sequencing a Human Genome.

⁴ Ernest Moniz, U.S. Secretary of Energy. Supercomputers Join the Fight Against Cancer. June 15, 2016.

machine learning, and artificial intelligence are rapidly becoming ubiquitous in consumer products.⁵ And these are just the technologies of *today*.

Perhaps most importantly, the Cancer Moonshot reflects a shared national commitment to harness the vast intellectual creativity and innovation of the American people to work together to take on the scourge of cancer. The promise of translating research gains into improved treatment options, such as the emergence of precision medicine, coupled with the signing of the Affordable Care Act to expand insurance coverage, the encouraged use of EHRs for patient care, and transitioning to new models of coverage and payment that promote better care at lower cost have provided an important foundation. The Cancer Moonshot aims to realize this promise by leveraging public and private efforts focused on building a system in which patients, researchers, and clinicians can seamlessly share information on treatments and outcomes to accelerate research, guide treatment decisions, and improve cancer outcomes for people across the Nation, and ultimately the world.

The time is now. Together, we can end cancer as we know it.

⁵ Jason Furman, Chairman Council of Economic Advisors. Is This Time Different? The Opportunities and Challenges of Artificial Intelligence. July 7, 2016.

The Launch: Establishment of a Cancer Moonshot Task Force

President Obama established a first-of-its-kind Cancer Moonshot Task Force (the “Task Force”) uniting 20 federal departments, agencies, and White House Offices under Vice President Biden’s leadership in the fight against cancer⁶. The Task Force was charged with leveraging federal investments, targeted incentives, private sector efforts, patient engagement initiatives, and more, to support cancer research and enable progress in prevention, screening, and treatment. These collective efforts are not intended to replace existing cancer programs, initiatives, and policies already underway, but instead are focused on areas in which a coordinated effort can dramatically accelerate the pace of progress in the fight against cancer.

Concurrent with the launch of the Task Force, President Obama proposed an additional \$1 billion investment by the Federal Government to jumpstart the initiative:

- \$195 million targeted for cancer activities aligned with the priorities of the Cancer Moonshot at the National Cancer Institute (NCI) in Fiscal Year 2016.
- \$755 million in proposed funds for new cancer-related research activities at both the National Institutes of Health (NIH) and the Food and Drug Administration (FDA) in Fiscal Year 2017 (budget request).
- Increased investments by the Department of Defense (DoD) and the Department of Veterans Affairs (VA)—the Nation’s largest public health care providers—by supporting Centers of Excellence focused on specific cancers and by conducting large long-term studies in the military and Veteran populations to define cancer risk factors and improve treatment.

President Obama’s Memorandum also directed the Task Force to consult with external experts, including the presidentially appointed National Cancer Advisory Board (NCAB). To ensure that the mission of the Cancer Moonshot was grounded in the best science, the NCAB formed a Blue Ribbon Panel. Recommendations made by the Blue Ribbon Panel detailing the scientific areas that will benefit from additional funding, support, and coordination were accepted by the NCAB and are described in an accompanying report. The scientific goals outlined in that report are highly synergistic with the areas described throughout this report and are intended to complement the Task Force’s plans.

The Task Force also identified ways in which the Cancer Moonshot could build on the critical accomplishments of this Administration in improving our understanding of cancer and access to cancer care. The President’s aggressive push to increase biomedical research funding generally, and the launch of programs like the Brain Research through Advancing Innovative Neurotechnologies (BRAIN) Initiative and the Precision Medicine Initiative (PMI) more specifically, has injected new money and enthusiasm into efforts in genomics, proteomics, technology development, data science, and immunotherapy. Critically, the landmark Affordable Care Act has provided coverage for the uninsured, eliminated discrimination based on pre-existing conditions such as cancer, begun to close the gaps in coverage for

seniors needing cancer drugs, and improved access to one of the most effective tools we have against cancer—prevention screenings—without cost sharing.

However, the Cancer Moonshot is a call to action, and its mission cannot be achieved by the Federal Government working alone or in isolation. Thus, in its deliberations, the Task Force sought new ways of mobilizing partnerships with the private sector and created new opportunities for collaboration. Additional private sector collaborations and efforts spurred by the Vice President's leadership, in addition to his vision for igniting new innovation within the biomedical research enterprise, are outlined in an accompanying executive report. In sum, the Cancer Moonshot reflects the widespread commitment of the Federal Government, the private sector, scientific researchers, nonprofit organizations, advocates, patients, families, and more working together to catalyze innovation, accelerate progress, and continuously disseminate and act on new knowledge to improve the lives of those facing cancer.

Charting the Course: Organizational Framework

The mission of the Cancer Moonshot—to make a decade’s worth of progress in preventing, diagnosing, and treating cancer in just 5 years—requires renewed efforts across the spectrum of cancer research and care. Thus, the Cancer Moonshot Task Force prioritized early in its discussions the need to have an organizational framework for addressing and uniting these efforts, centered on improving outcomes for patients. In doing so, five strategic goals emerged, which are discussed in further detail in Section IV of this report. Each goal is not only critical to the overall mission, but also is intended to build on and augment the success of the other goals. It is the coordinated effort across these areas that will ultimately improve the lives of cancer patients and their families.

Task Force members agreed that this unique opportunity to usher in a new era of cancer prevention, diagnostics, and therapies can only be achieved if the entire cancer ecosystem works together in new and innovative ways. Efforts pursued under the Cancer Moonshot must complement and build on activities currently underway, but cannot be “business as usual.” The Task Force agreed that to be a “moonshot” any new pursuit must serve a bold purpose and embody a set of core principles that will ensure each effort undertaken has the maximum impact for the community and the individual patient. The following principles are embedded within each strategic goal and throughout the Task Force’s actions and recommendations:

Cancer Moonshot Strategic Goals

- Catalyze New Scientific Breakthroughs
- Unleash the Power of Data
- Accelerate Bringing New Therapies to Patients
- Strengthen Prevention and Diagnosis
- Improve Patient Access and Care

- Drive innovation in the current cancer ecosystem by pursuing audacious, creative, and disruptive approaches;
- Collaborate across disciplines, sectors, and borders to leverage talent and expertise; and
- Share information rapidly to drive advances and crowdsource solutions.

Under the framework established above, the Task Force immediately began working within and across federal departments and agencies to launch a series of focused actions and collaborations to harness resources, programs, personnel, and technology in support of achieving the Cancer Moonshot mission. It established an interagency working group comprising senior leadership across the Federal Government that met bi-weekly to share ideas, discuss challenges, identify new collaborations, and propose new catalytic efforts. Ultimately, the effort engaged staff at multiple levels across the entire Federal Government, demonstrating the deep commitment at all levels to achieve the vision for the Cancer Moonshot as set forth by President Obama and Vice President Biden. Accomplishments spurred by these conversations are described in detail in the next section of this report, along with implementation plans for future activities that can continue to further the Cancer Moonshot’s mission.

Liftoff: Cancer Moonshot Implementation Plan

Many of the Cancer Moonshot activities proposed by the Task Force have already taken shape in 2016. Some were launched at the Cancer Moonshot Summit in June 2016 (see Igniting a National Conversation), while others were launched throughout the year. These efforts are described in further detail in the following sections.

Igniting a National Conversation: Cancer Moonshot Summit

The Cancer Moonshot Summit was convened on June 29, 2016, at Howard University in Washington, D.C. At the event, the Vice President spoke to individuals and organizations representing the entire cancer community and beyond who came together to identify ways to double the rate of progress toward ending cancer as we know it. More than 35 initiatives were announced, reflecting commitments from federal agencies and private sector organizations—industry, nonprofits, foundations, health care systems, and academic institutions—each taking on a piece of the blueprint for the overall Cancer Moonshot mission. In addition, the event inspired more than 300 local summits across all 50 states, Puerto Rico, Guam, and Washington, D.C., engaging more than 7,000 individuals to discuss how they #CanServe by commitment to the goals of the Cancer Moonshot and contributing what they are able.

Plans for continuing momentum under the Cancer Moonshot are provided below as a “blueprint” for future Administrations. These proposals are not intended to be a budget document, as all activities are subject to budgetary constraints and other approvals, including the weighing of priorities and available resources by the Administration in formulating its annual Budget and by Congress in legislating appropriations. However, they are intended to make clear the opportunities on the horizon and the importance of the President’s \$1 billion proposal to invest in the Cancer Moonshot.

Strategic Goal 1 – Catalyze New Scientific Breakthroughs

We are witnessing widespread and unprecedented optimism that we are on the verge of pivotal advances in oncology research. This view is based on progress in many areas, including immune-based and targeted therapies, genomics and precision medicine, advanced imaging technologies and other technological innovations, new cell-based and animal preclinical cancer models, greater understanding of the causes and molecular pathogenesis of cancer, and more. As we gain an increasing understanding of basic biology, it becomes readily apparent that greater collaboration across scientific disciplines can propel a more in-depth knowledge of what is possible. Whether it be through understanding the physical properties catalyzing cell movements or the use of nanotechnology to deliver the next critical treatment option, science will be key in driving new options for improving the lives of patients.

Research related to cancer is supported by numerous federal agencies represented on the Cancer Moonshot Task Force and the current understanding of cancer is a direct result of years of public and private investment in basic, translational, and clinical science. But more can be done to catalyze new scientific breakthroughs. Under the Cancer Moonshot, the Federal Government is prioritizing interdisciplinary approaches to elucidate the biological mechanisms underlying cancer onset and

treatment, aligning research and care as a seamless and iterative process, pursuing multidisciplinary initiatives, and maximizing the collection and research use of longitudinal data and biospecimens. Much of this aligns with the Blue Ribbon Panel's 10 recommended areas of scientific opportunity for NCI investment as part of the Cancer Moonshot (see Blue Ribbon Panel below).

Blue Ribbon Panel Recommendations

Network for direct patient engagement. Engage patients to contribute their comprehensive tumor profile data to expand knowledge about what therapies work, in whom, and in which types of cancer.

Cancer immunotherapy translational science network. Establish a cancer immunotherapy clinical trials network devoted exclusively to discovering and evaluating immunotherapy approaches.

Therapeutic target identification to overcome drug resistance. Identify therapeutic targets to overcome drug resistance through studies that determine the mechanisms that lead cancer cells to become resistant to previously effective treatments.

Creation of a data ecosystem for sharing and analysis. Create a national ecosystem for sharing and analyzing cancer data so that researchers, clinicians, and patients will be able to contribute data, which will facilitate efficient data analysis.

Fusion oncoproteins in pediatric cancer. Improve our understanding of fusion oncoproteins in pediatric cancer and use new preclinical models to develop inhibitors that target them.

Symptom management research. Accelerate the development of guidelines for routine monitoring and management of patient-reported symptoms to minimize debilitating side effects of cancer and its treatment.

Implementation of evidence-based approaches to prevention. Reduce cancer risk and cancer health disparities through approaches in development, testing, and broad adoption of proven prevention strategies.

Retrospective analysis of biospecimens from patients treated with standard of care. Predict response to standard treatments through retrospective analysis of patient specimens.

Creation of human tumor atlas. Create dynamic 3-D maps of human tumor evolution to document the genetic lesions and cellular interactions of each tumor as it evolves from a precancerous lesion to advanced cancer.

Technology development. Develop new enabling cancer technologies to characterize tumors and test therapies.

Year 1 Accomplishments and Plans

During the first year of the Cancer Moonshot, the Task Force established the foundation for new and more efficient scientific collaborations across federal departments and agencies, leveraging the expertise and reach of each toward a common goal. Efforts launched by the Task Force in Year 1 of the Cancer Moonshot include:

- ***Expediting Researchers' Access to Cancer Compounds for Research – NCI's Drug Formulary***

Leveraging lessons learned through the NCI-MATCH (Molecular Analysis for Therapy Choice) clinical trial in which agents developed by different companies are tested alone or in combination under a single study, NCI is forging a public-private partnership with 20 to 30 pharmaceutical and biotechnology companies to expedite cancer researchers' access to investigational agents and approved drugs. Researchers will be able to obtain compounds through one pre-approved "formulary" list and test them for new purposes or in new combinations, thereby alleviating the need to negotiate with each company independently for individual research projects, which can take as long as 18 months. Ultimately this approach will expedite the start of clinical trials and will bring new options to cancer patients faster. The first agents are expected to be available to the research community by the end of the year.

- ***Strategic Computing Partnership Between the Department of Energy (DOE) and NCI to Accelerate Precision Oncology***

In partnership with NCI, DOE launched three new pilot projects bringing together nearly 100 cancer researchers, care providers, computer scientists, and engineers to apply the Nation's most advanced supercomputing capabilities to analyze data from preclinical models in cancer, molecular interaction data for RAS genes, and cancer surveillance data. Four DOE National Laboratories will conduct the work—Argonne, Los Alamos, Lawrence Livermore, and Oak Ridge—in conjunction with the NCI Frederick National Laboratory for Cancer Research. By joining these forces under a coordinated effort, these projects will refine our understanding of the mechanisms leading to cancer development and thereby accelerate the development of promising therapies that are more effective and less toxic.

- ***DoD Launching Groundbreaking Longitudinal Study to Revolutionize Precision Oncology***

DoD is establishing a groundbreaking new longitudinal study to transform our understanding of the biological underpinnings of cancer. Using the vast amount of data housed within DoD's cancer registry and serum repository, researchers will work to identify new linkages between pre-diagnostic biological markers and various types of cancer. Approximately 1,000 new cases of cancer occur annually in active duty personnel, and there are approximately 250,000 samples from the last 25 years available to undergo protein signature analysis for pre-incident cancer markers. DoD and the Environmental Protection Agency (EPA) will also work in partnership to link results with the "Environmental Quality Index" to further evaluate the environmental factors contributing to this disease.

- ***Preclinical Research Partnership to Evaluate the Potential of Particle Beam Radiotherapy***

The National Aeronautics and Space Administration (NASA) and NCI are establishing a new collaboration to study the biological effects of particle beam radiotherapy, a novel technology that may deliver a more targeted dose of radiation to tumor cells. Currently, NCI supports several efforts in this area, including comparing the efficacy of carbon ion therapy for the treatment of pancreatic cancer, and NASA is studying the biological effects of a wide range of heavy ions to develop countermeasures for protecting astronauts from the space radiation environment. Under this new partnership, agencies will share data and biospecimens to assess the biological effects of particle beam radiotherapy and evaluate its potential value as a new approach to fighting cancer.

Plans for Year 2 and Beyond

To accomplish the priorities under this Strategic Goal, in addition to the 2016 initiatives described above, several plans for the long term are proposed.

1. *Strengthen interactions among agencies and engage additional partners in support of multidisciplinary basic cancer research.*

The complexities of cancer require a multidisciplinary and integrated approach to research. Efforts will be made to inform approaches to molecular modeling by facilitating more formal and robust interactions among mathematicians, modelers, synthetic biologists, and more traditional cancer researchers. These efforts could expand to include DOE, FDA, and NASA. Building on existing agreements, the principal agencies will support a series of workshops to bring multiple disciplines together around key aspects of basic cancer research. An initial workshop was held in October 2016 involving cancer researchers and systems and synthetic biologists to discuss how to engineer the immune system. An IDEAS Lab on topics identified in this first workshop, modeled after the IDEAS Lab on physical and computational approaches to clinical cancer research—jointly funded by a public private partnership involving the National Science Foundation (NSF), NCI, Stand Up to Cancer, and the V Foundation—will be used to catalyze research investments in areas identified in this first workshop. Additional workshops, followed by funding opportunities such as IDEAS Labs, are intended to be developed each year, depending on the availability of funds. The first projects are proposed to be funded in Fiscal Year 2018.

2. *Expand the implementation of mobile devices and wearable technologies for cancer diagnosis and treatment.*

Several DoD efforts focused on developing new technologies will be leveraged to fight the war on cancer. First, two projects will center on developing new nanotechnology to increase our ability to visualize and treat cancers at their earliest signs of development. This includes developing imaging systems for real-time analysis to detect microscopic cellular changes, and new laser devices to precisely target surgical interventions in a safer and less invasive manner. Additional projects will develop new technologies and platforms for tracking cellular changes over time, to alert patients and physicians of the earliest stages of cancer onset. These include automated and sensitive systems for tracking changes in moles that indicate future melanomas, and mapping tissue oxygenation to detect and optimize the treatment of cancer throughout the course of therapy. An additional project will develop a "cellular highlighter" to help researchers track the molecular, genomic, and proteomic signatures of cells that appear resistant to cancer treatments. By isolating and analyzing these cells, we can begin to understand the mechanisms underlying treatment-resistant cancers and develop more targeted therapies for affected patients.

3. *Create a high-quality performance status tracking system for cancer patients during therapy and long-term follow-up.*

A joint effort between NCI and DoD is aimed at improving the lives of cancer patients undergoing treatment, as well as members of the military attempting to complete a mission. Both cancer patients and military personnel suffer similarly from physical, physiological, and environmental stressors that affect their ability to perform as they each face potentially life-threatening challenges. An accurate, quantitative assessment could prevent doctors from

sending patients for treatment they are not healthy enough to endure—and could help commanding officers avoid sending military personnel on missions they are not healthy enough to complete. The Analytical Tools to Objectively Measure Human Performance (ATOM-HP) project will create a high-quality performance status tracking system for cancer patients during therapy and long-term follow up. The goal is to be able to assess, in real time, a cancer patient's experiences with physical, psychological, and environmental factors, among others. This is expected to advance the ways by which doctors can monitor core dynamics in cancer patients on a regular basis.

Strategic Goal 2 – Unleash the Power of Data

Data come in all sizes, shapes, and forms, and making sense of this information is essential for developing any new and effective approach to combatting cancer. Today researchers are working with an unprecedented amount of data, in part due to the explosion of genomic information, increasing use of EHRs, and large datasets of clinical, environmental, and public health information. This new era provides a tremendous opportunity for cancer research and care, but also raises significant challenges. Privacy and security issues must be at the forefront of discussions and policy decisions. Making sense of large volumes of data with varying complexity—often referred to as “Big Data”—requires advanced computational capabilities. It is also imperative that data and the insights its analyses generate are rapidly shared as appropriate with researchers, physicians, caregivers, and patients to guide new discoveries and treatment decisions.

Under the Cancer Moonshot, the Task Force is unleashing the power of data to enhance, improve, and inform the journey of every cancer patient from the point of diagnosis through survivorship. To realize this ambitious goal, three priority areas are being tackled: (1) enabling a seamless data environment through shared policies and technologies, (2) unlocking scientific advances through open computational and storage platforms and next generation computer architectures, and (3) developing a workforce capable of using the open and connected data environment. Ultimately, smart collection and use of data can enable the creation of a “learning health care system for cancer,” where as a Nation we learn from the contributed knowledge and experience of every cancer patient.

Year 1 Accomplishments and Plans

The Task Force launched several foundational initiatives in the first year of the Cancer Moonshot to further the vision of establishing a national learning health care system for cancer. Efforts in Year 1 include:

- ***Creation of an Open Access Resource for Sharing Cancer Data via the Genomic Data Commons***

As part of the Cancer Moonshot and the President's Precision Medicine Initiative (see box), Foundation Medicine is more than doubling the total number of patients represented within the NCI's Genomic Data Commons (GDC), bringing its total to over 32,000 patients accumulated in just over a month. At its launch in early June, the GDC already shared more than five petabytes of raw unprocessed genomic data from large research projects on nearly 30 tumor types from more than 14,000 patients, along with associated clinical data (e.g., clinical diagnosis, treatment history, survival data), creating a foundational system for broad sharing and analysis of cancer genomic data, which is critical for advancing the field of precision medicine and improving the care of cancer patients.

The GDC is complemented by the NCI Genomics Cloud Pilots, which were recently funded for an additional year with the goal of co-locating the computational tools developed by the three Cloud Pilots with the GDC to create a cohesive model for large-scale genomic data management and analysis. The pilots also aim to expand the GDC to other data types, such as proteomics or imaging data. The Cloud Pilots are an important part of exploring new mechanisms for data access, computation, and analysis for cancer data. The Pilots are a partnership of The Broad Institute, The Institute for Systems Biology, and Seven Bridges Genomics. They went public in Spring 2016 and are under active evaluation through September 2017. Most recently, as part of the Cancer Moonshot, NCI jointly announced a new public-private partnership designed to build a sustainable model for maintaining cancer genomic data in the cloud for use by cancer researchers through the GDC and the Genomics Cloud Pilots.

President's Precision Medicine Initiative

Precision medicine is an emerging approach for disease prevention and treatment that takes into account individual variability in genes, environment, and lifestyle. While we have seen important successes in precision medicine, notably in cancer, the practice is not currently in use for most diseases.

To expedite progress on this front, on January 30, 2015, President Obama launched the Precision Medicine Initiative as a bold new effort focused on catalyzing advances in personalized care. As part of this effort, NIH is supporting a precision oncology component, which focuses on using tumor samples and clinical information from patients to study the development and spread of cancer, elucidating the cellular and molecular changes that give rise to cancer, understanding treatment responses and therapeutic resistance, developing the national information technology infrastructure for future clinical trials, and testing targeted cancer therapies in partnership with patients nationwide through the NCI-MATCH (Molecular Analysis for Therapy Choice) Trial. Taken together, this national effort mobilizes researchers, providers, and patients to work together in partnership to develop individualized care.

- ***Harnessing Big Data to Transform Veteran Health through Precision Medicine***

VA and DOE formed a new collaboration to apply the most powerful computational assets at DOE's National Labs to more than half a million Veterans' records from one of the world's largest research cohorts—the Million Veteran Program, a cornerstone of the President's Precision Medicine Initiative. This is a 5-year, renewable commitment with \$3.5 million allocated in Fiscal Year 2016. The first phase of this partnership will focus on cancer, cardiovascular disease, and mental health issues, and the resulting platform will accelerate our understanding of disease detection, progression, prevention, and treatment by combining the rich clinical, environmental, and genomic data—all while enabling top researchers in the world to perform the most cutting-edge science.

- ***Tri-Agency Coalition to Enhance Cancer Care – Applied Proteogenomics Organizational Learning and Outcomes (APOLLO) Consortium***

DoD, VA, and NCI formed a new collaboration using state-of-the-art research methods in proteogenomics to more rapidly identify unique targets and pathways of cancer for detection and intervention—a critical big data challenge. These methods will look at a patient’s genes that may lead to cancer and the expression of these genes in the form of proteins, with potential impact on disease formation and treatment for cancer patients. Initial collaborative efforts will focus on a cohort of 8,000 lung cancer patients within the Nation’s two largest health care systems and will make data broadly available to the research community. Ultimately, the effort will be expanded to additional cancer types to reach more cancer patients within VA and DoD, providing knowledge scalable for physicians across the country treating the more than 1.6 million new patients diagnosed with cancer each year.

Plans for Year 2 and Beyond

The Task Force anticipates that the activities described above will continue to grow and expand in scope into Year 2 and beyond, as discussed below. To build on and sustain this momentum, efforts and resources will be needed for developing:

- Best practices for appropriately and respectfully obtaining consent from patients to use their data, and mechanisms for patients to access their health records and contribute them to research such as Sync for Science and Blue Button;
- Effective strategies for generating data standards, especially in cases where there are no existing organizational frameworks;
- Additional mechanisms for making data shareable, especially across multiple repositories and registries, that include approaches to protect data privacy and security;
- New computational and organizational capabilities for obtaining scientific understanding from complex datasets;
- Enhanced strategies for accelerating the translation of basic scientific findings to improved patient outcomes;
- Platforms and collaborations that bring together private-sector data scientists and cancer researchers, such as through data challenges; and
- Incentives for embedding data science training within the research career path and supporting the next generation of data scientists.

Much of the groundwork for these efforts was laid in 2016, with opportunities for sustaining and augmenting them described below.

1. *Rapidly analyze the molecular profile of thousands of tumors.*

Advances in molecular profiling of patients are difficult to test and rapidly deploy in the current translational pipeline. The APOLLO network (see above) will strengthen and develop research cooperation in using state-of-the-art methods in proteogenomics to characterize and compare tumors, develop a deeper understanding of cancer biology, and identify potential targets and pathways of cancer prevention, detection, and intervention. Developing these methods will lead to better diagnostic tools and effective treatments once disease pathways are discovered.

Collaborations between the APOLLO consortium and the new DoD and VA Infrastructure for Clinical Intelligence (DAVINCI) project will synergize the data-sharing infrastructure. Protocols for data sharing will be reviewed by appropriate Institutional Review Boards and pilot projects will validate the feasibility of sharing existing samples. Ongoing prospective tissue collection will occur into the next 3 years as will mergers with APOLLO genomic and proteomic workflows.

2. *Create a shared resource of linked clinical datasets.*

Linked clinical datasets, with appropriate and required privacy and security measures, would facilitate better care and potentially and sharing of data for research. Such a resource should link a wide range of datasets, for example, vaccine registries, HIV registries, or administrative data, as well as include a mechanism to identify cancer patient cohorts. Initially, DOD and VA will share data from their respective enterprise data warehouses (medical management and registry capabilities), an effort that has been pioneered in the DAVINCI project. Sharing computable data derived from the two departments' respective EHRs in a mutually understood data model is one early capability of this effort.

Existing policy and agreements between the departments enable the secure sharing of protected data from the millions of patients who have received care in both systems, which includes nearly all Veterans. Expanding this system will enable a Veteran's health record to be augmented with his or her active duty health record. In the future, the architecture may be expanded to include additional datasets such as radiologic images, and, with appropriate access management and subject consent, data collected in joint research projects. DAVINCI sustainment will be addressed through ongoing modernization and rationalization of the DoD health information technology (IT) portfolio. Resources will be needed to accommodate new use cases as well as currently recognized registry support.

3. *Improve the clinical data available for research by creating a tool that converts narrative into standardized data.*

Despite the development and implementation of data standards over the last decade, some health data stored in medical records, laboratory reports, and other clinical reports are only available in free-form text narratives (e.g., clinical notes). Over the next 2 years, the Centers for Disease Control and Prevention (CDC) and FDA will collaborate to create a Natural Language Processing (NLP) Web Service that accepts different types of unstructured health data and returns standardized data for easier integration into databases. When clinical information is incomplete and not available to researchers because it is in narrative rather than data form, research is stymied. This initiative intends to build a resource that can help to solve that problem by converting text into data, which would then be available for quantitative analysis. The NLP Web Service would complement current standardization work. An extensive review of published and existing NLP activities needs to be conducted for possible inclusion on the NLP Web Service, which will be built on a shared platform. Once developed, FDA and CDC intend to pilot test it using cancer data from CDC and surveillance data for blood products and vaccines from FDA. FDA and CDC anticipate that the findings from the pilot project will be used to develop guidance for other federal agencies, public health agencies, academic centers, and commercial vendors as they transition the NLP Web Service into practice. Of note, the NIH-supported Biportal Annotator API and the NIH Big Data to Knowledge (BD2K) activities include a number of relevant capabilities.

4. *Advance secure and scalable platforms for data and metadata management for sharing and analysis.*

Extracting meaningful molecular data from patients with cancer poses significant challenges: data are of different types, they are often stored in disparate repositories, and they contain private information that must be protected. Surmounting these challenges will require collaborative and cooperative efforts to advance secure and scalable platforms for data and metadata management, sharing capabilities for distributed teams of scientists (or virtual organizations), and customized analysis pipelines for high-performance and cloud computing.

The NSF-funded CyVerse project has developed and deployed a cyberinfrastructure platform that currently incorporates state-of-the-art features that could be adapted to meet many of these challenges. CyVerse leadership will host a summit in Winter 2017 to bring together leaders of federal cancer-related projects to discuss common needs and challenges and to explore how capabilities such as those incorporated in the CyVerse platform could meet the challenges. A foreseeable outcome of the summit would be development of ideas for a pilot project to facilitate scalable analysis while preserving privacy of cancer-related datasets used for genotype-to-phenotype analysis via high performance computing workflows. Development of the pilot and submission of a proposal to test it could be completed 60 to 90 days after the workshop. One follow-on activity could carry out the pilot to test enhanced abilities to store, share, and analyze data in a secure environment and to appropriately deliver results to investigators or clinicians while preserving privacy of the underlying data. Next steps could include issuing new solicitations for proposals at the interface of the biological and computational sciences that would leverage and expand capabilities for large-scale analysis of cancer data, with the aim of enabling discovery of the basic underpinnings of cancer development and progression. The results of this research would complement and enhance the predictive capabilities of efforts supported by partner agencies.

5. *Develop predictive computer algorithms to rapidly develop, test, and validate predictive preclinical models.*

Combined efforts across NCI and DOE will provide a practical, scalable approach to preclinical screening aimed at opening up new therapeutic options for cancer patients. These models will seek to support the treatment choices of physicians and patients with the goal of achieving the best possible clinical outcome. To lay the groundwork for this effort, a Memorandum of Understanding between DOE and NCI was established in July 2016. It outlines the agencies' intentions to collaborate in developing a shared technology ecosystem and targeted applications to bring advanced computing capabilities to biological research, thereby transforming drug and treatment development and improving patient care and outcomes. NCI and DOE will begin by: (1) identifying key data gaps, (2) developing initial frameworks and reference implementations, (3) establishing standards of use for data to support model development, and (4) extending involvement to other agencies, academia, and industry. The partnership then aims to develop a set of models that can predict drug responses across a range of cell lines and intends to develop an approach for integrating mechanistic models and mechanism-based constraints into the machine learning framework.

6. *Build collaborative relationships with the private sector and academia.*

Academic partners not only bring scientific and medical expertise, but they also can provide a richness of data tied to their patient care needs. The technology sector can help co-develop next

generation instruments and technologies at many scales that can be driven by the priority questions being tackled. Drawn together, these can be important resources for unleashing the power of data in cancer treatment. Currently, the University of California, Intel, IBM, and General Electric have engaged DOE and NCI to build on their existing resources, technologies, tools, data, collaborations, and governance expertise to focus on the intersection of technology, cancer, and data. With this collective potential to collect, aggregate, integrate, share and analyze vast and diverse datasets, these partnerships could enable discoveries to transform cancer prevention, detection and diagnosis, accelerate therapeutic development, and advance a patient-centered learning health care system. The overarching vision includes a virtual data ecosystem (drawing from the UCHealth Data Warehouse, which brings together ~15 million patient records), The Parker Institute for Cancer Immunotherapy, Athena Breast Health Network, and the University of California's five NCI-designated comprehensive cancer centers, and potentially a physical co-location at the University of California, San Francisco, that unites researchers, physicians, engineers and computer scientists from academia, national laboratories, health centers and the private sector. This collaborative, synergistic framework will be a key driver for achieving precision medicine—with cancer at the leading edge. Such a regional center will serve as a powerful model, and hub, for national-scale activity.

7. *Create a knowledgeable, sustainable, and agile biomedical data science workforce.*

A multi-pronged approach is needed to address the skills and workforce gaps in biomedical data science, from early education exposure to data science of those being trained in the biomedical sciences, to educating established biomedical and clinical investigators about applying computation to biomedical research questions. It is important to note that successful efforts across the Federal Government to achieve these goals are underway and will continue to be a priority. However, to truly support biomedical data science, the Federal Government needs to send a strong signal to the academic community that the development of the tools and algorithms for data analysis is a valued and “legitimate” scientific discipline. This signal should come in the form of dedicated set-aside funding for biomedical data science undergraduate and graduate education by departments and agencies such as DOE, NIH, NSF, and NCI. Support should be included for:

- Undergraduate and graduate education programs
- Cancer data science curriculum development grants (including medical schools)
- Early career grants
- Grants to support integrated teams of biomedical/clinical experts and computational experts, building on efforts such as the NIH/NSF Innovation Lab and the NCI Applied Mathematics in Germinating Oncology Solutions (AMIGOS)
- Interagency fellowship programs to place data science fellows throughout the research and care continuum, building on efforts like VA's Big Data-Scientist Training Enhancement Program (BD-STEP) to expand to other agencies such as NSF, FDA, or CDC. This should include dedicated resources for VA to manage BD-STEP and build data science curricula and community
- Continuing education workshops in data science for biomedical scientists and physicians

Federal departments and agencies involved in the Cancer Moonshot must also have the capability to recruit top talent and provide training for existing staff for developing, deploying, and disseminating

novel technologies and best practices for big data analytics. This can be achieved by leveraging and scaling FDA's Information Exchange and Data Transformation (INFORMED) initiative.

Strategic Goal 3— Accelerate Bringing New Therapies to Patients

The development of lifesaving products for patients depends on the success of moving an idea from “bench to bedside.” The long arc of the commercialization lifecycle—for any product or breakthrough treatment—includes time, capital investments, intellectual property protections, licensing agreements, meaningful clinical trials, robust data analyses, and appropriate regulatory mechanisms that balance patients' needs with product effectiveness and safety. This process can be arduous for a researcher and frustrating for a patient, often costing too much money and taking too much time.

Under the Cancer Moonshot, a number of federal agencies have convened to find efficiencies in this process, whether it be through enhancing data sharing across sectors, incentivizing pre-competitive collaborations, strengthening the clinical research enterprise, or innovating patent review. For instance, the Task Force prioritized efforts to enhance participation in clinical research while keeping patient safety at the forefront. Through new efficiencies at the U.S. Patent and Trademark Office (USPTO) and new initiatives at FDA, the federal agencies are taking steps to ensure that all efforts are being made to accelerate the delivery of new safe and effective products to patients. DOE and NCI are leveraging high-performance computing applications to gain new insights into patient outcomes. And by releasing such data via third-party application programming interfaces (APIs), academics, application (app) developers, and others can further analyze the efficacy of treatments and develop additional tools for the public, while NIH and others bring new partnerships online to stimulate even more research.

Year 1 Accomplishments and Plans

In Year 1 of the Cancer Moonshot, the Task Force focused on accelerating the pace at which ideas get protected, manufactured, tested, and ushered to clinical treatment centers. Several of these efforts described below will require additional effort spanning the next few years, but the Task Force agreed that their initiation was critical in Year 1 to ensure the swift movement of discoveries to clinical care.

- ***Creation of a New Program to Accelerate Cancer Product Regulatory Review***

FDA hired an Acting Director of its new Oncology Center of Excellence (OCE). The OCE will unite cancer product regulatory review to enhance coordination and leverage the combined skills and clinical expertise across FDA centers. Under the Cancer Moonshot, the Acting Director is charged with accelerating the establishment of a program that brings together oncologists across the FDA in an effort to expedite the development of novel cancer-related drugs, biologics, and devices and support an integrated approach to tackling this devastating disease.

- ***NIH Public-Private Partnership for Accelerating Cancer Therapies***

NIH is collaborating with 12 biopharmaceutical companies, multiple research foundations, philanthropies, and the Foundation for the NIH to develop a new program under the Cancer Moonshot, the Partnership for Accelerating Cancer Therapies (PACT). PACT will fund pre-competitive cancer research and share broadly all data generated for further research, ultimately bringing more new therapies to patients in less time. Potential initial focus areas include understanding responses to cancer therapies, clinical trial platforms for combination therapies, predictive modeling approaches, and therapies for rare cancers.

Companies involved in the design of PACT include GlaxoSmithKline, Bristol-Myers Squibb, Boehringer Ingelheim, Eli Lilly, EMD Serono, Amgen, Takeda, Genentech, Novartis, Bayer, Merck, Pfizer, AbbVie, and AstraZeneca. Through consultation with PACT partners, NIH identified two focus areas ideally suited to such a multi-sector and coordinated effort: (1) identification and validation of biomarkers for response and resistance to cancer therapies, with a special emphasis on immunotherapies; and (2) establishment of a platform for selecting and testing combination therapies. The first focus area will address fundamental gaps in our understanding of how cancer therapies, especially immunotherapies, work in patients, and enable precision monitoring of a patient's progress during treatment. The second effort will take a collaborative approach to identify and test new combinations of the collective toolkit of the pharmaceutical industry. For both efforts, NIH will serve as a hub of coordinated efforts and information sharing across public and private sectors. A draft plan for specific potential projects, milestones, and timelines for completion will be finalized and shared with potential PACT partners by early December 2016.

- ***Forging New Partnerships to Catalyze New Drug Discovery and Development***

DOE, NCI, and GlaxoSmithKline are engaged in a new public-private partnership designed to harness high-performance computing and diverse biological data to accelerate the drug discovery process and bring new cancer therapies from target to first-in-human trials in under 1 year. This partnership will bring together scientists from multiple disciplines to advance our understanding of cancer by finding patterns in vast and complex datasets to accelerate the development of new cancer therapies.

- ***Patents 4 Patients: Establishment of Fast-Track Review for Cancer Treatment-Related Patents***

In June the USPTO launched a free and accelerated pilot program that aims to cut in half the time it takes to review patent applications in select fields of cancer therapy (in less than 12 months). This "fast track" is open to any applicant, including early-stage biotechnology companies, universities, and large pharmaceutical firms alike, and entities who have products already in FDA-approved clinical trials will be able to opt into the acceleration program. With approximately 900 applications received annually from around the world in the cancer immunotherapy space alone, this pilot program aims to catalyze innovative new treatments from conception through regulatory approval in order to reach the patient's bedside faster.

- ***Crowdsourcing Intellectual Property Data to Guide Cancer Investments***

In September, USPTO launched the "USPTO Cancer Moonshot Challenge" to use intellectual property datasets to map and identify trending cancer technologies, enabling more precise funding and policy decisions regarding promising new treatments. With data and a new Cancer Treatment/Therapy API released through the USPTO Developer Hub, the challenge empowered app developers, academics, and coders to build rich visualizations of patent data—often an early indicator of meaningful R&D—and combine them with other economic and funding datasets. In September, USPTO and the Office of Science and Technology Policy announced three winners of the prize challenge who presented data-driven findings focused on how genetics and epidemiology of cancer relate to rates of patenting of diagnostics, and how federal funding of cancer research is amplified by dissemination of discoveries through patenting.

- ***Making Clinical Research Trials More Accessible to Cancer Patients***

NCI, in partnership with the White House Presidential Innovation Fellows, is re-designing how patients and oncologists learn about and find information about cancer clinical trials. The goal is to ensure that patients and their care teams have access to the information they need at the right time, as well as strengthen participation in cancer research studies to help accelerate medical discoveries and treatments for cancer. The first phase will make cancer clinical data hosted on cancer.gov available through an API for advocacy groups, academia, and others in the cancer ecosystem to access directly. The API will enable third-party innovators, including Smart Patients, Syapse, Cure Forward, and Trial Reach, to use the new cancer clinical trial API to build applications, integrations, search tools, and digital platforms tailored to individual communities that bring clinical trial information to more providers, patients, and their family members.

- ***Strengthening and Clarifying the Requirements for Public Availability of Clinical Trial Information***

In September, the Department of Health and Human Services (HHS) issued a final rule for clinical trial registration and results information submission to ClinicalTrials.gov, a database of publicly and privately supported clinical studies of human participants conducted around the world, to increase the availability of information about ongoing clinical trials and summary results. NIH and FDA also announced a series of efforts and policies accompanying the rule to improve the quality and efficiency of clinical research, including activities focused on helping people find trials, enhancing clinical trial design, and increasing the efficiency of the drug and device development process. Ultimately these efforts will help prevent the unnecessary duplication of unsuccessful or unsafe trials, increase the efficiency of drug and device development processes, improve clinical research practice, and build public trust in clinical research.

Plans for Year 2 and Beyond

Efforts focused on augmenting Year 1 accomplishments include:

1. ***Modernize eligibility criteria for clinical trials.***

In coordination with the American Society of Clinical Oncology, Friends of Cancer Research, and other stakeholders, FDA will evaluate clinical trial entrance criteria that may unnecessarily restrict clinical trial access—such as brain metastases, HIV status, organ dysfunction, and age restrictions (e.g., pediatrics)—to better assess when restrictions are warranted for specific clinical trials to protect patient safety. Safely removing certain exclusion criteria and broadening eligibility criteria would render the results of clinical trials more generalizable to the actual patients who will receive drugs in clinical practice and provide patients with access to promising new drugs. Moving forward, FDA will work with sponsors to improve the use of science-based, clinically relevant eligibility criteria to allow greater patient access to clinical trials while maintaining patient safety. This project is currently underway and should be completed over the next 1 to 2 years.

2. ***Pilot large simple trials.***

Large simple trials have been conducted in certain therapeutic areas, such as cardiovascular diseases, frequently using overall survival as the trial's primary endpoint. These trials focus on clinically relevant, easily evaluated endpoints and minimize the data elements to be collected

throughout the clinical trial. Therapies evaluated in these trials generally have been evaluated in previous clinical trials with a prior safety profile being demonstrated. Because of this prior experience with these therapies, extensive new data collection may be unwarranted. These trials also have less restrictive entrance criteria and reflect the clinical practice situations where these therapies will actually be used. Within the next year, FDA plans to convene a meeting or workshop for industry and other stakeholders to discuss novel trial designs and aims to obtain commitments from several sponsors to pilot such designs.

3. *Develop site/tissue agnostic trials and broaden indications.*

Oncology has conventionally been organized with a specific disease/organ site orientation, which is reflected in the design of clinical trials (e.g., breast cancer trials, lung cancer trials, colon cancer trials). With the advent of molecular profiling of tumors, we now know that cancers from a wide variety of disease sites may share the same actionable mutation or marker. Hence, clinical trials focused on a molecular target or marker independent of the disease site—"tissue or site agnostic"—may be necessary to evaluate these targeted therapies in a wide array of conventionally defined organ site diseases. To expedite the development of novel therapies for a broader range of oncology indications, clinical trials encompassing multiple different cancers (site agnostic) with the same molecular target are being conducted in a single trial. These trials are presently exploratory trials and greater clarity is needed to develop the regulatory approach for drug approval of these site agnostic indications. The NCI MATCH trial and the Pediatric MATCH trial will contribute to our understanding of how these trials should be run and evaluated. Within the next year, FDA will convene a workshop on this topic and sustain engagement with sponsors to facilitate the development of site agnostic trials.

4. *Increase the usage of common control and expansion cohort trials.*

To date, the gold standard clinical trial for a commercial sponsor is to compare an individual investigational new product to a standard control arm in a randomized trial. However, clinical trials using a common control with the investigational arm comprising multiple agents of the same therapeutic class from different commercial sponsors would decrease the number of patients needed for enrollment and reduce time to completion of the trials, while providing the same statistical rigor in formulating decisions. Such expansion cohort trials already have been used in the development of PD-1 immunotherapies, and significantly reduced time and regulatory expenditures compared to the conventional Phase 1/Phase 2/Phase 3 approach. As part of the Cancer Moonshot, FDA will take the lead in encouraging sponsors to consider this type of trial design as well as discussing these designs at upcoming conferences, recognizing that clarification from FDA on the design, conduct, and regulatory submission of common control trials would foster interest from commercial sponsors and decrease cost and completion time of trials.

5. *Achieve greater interaction with pharmaceutical sponsors on international trials.*

Currently, pharmaceutical sponsors engage both U.S. and foreign investigators to establish clinical trial sites and generate trial accrual. Commercial sponsors frequently accrue a vast majority of patients from foreign trial sites. Not only does this lack of U.S. patients reduce the access of novel investigational agents to U.S. patients, but also data generated from these trials may not reflect the broader patient population, especially racial and ethnic subgroups that will use the drug when approved in the United States. To enhance the number of clinical trials

conducted in the United States and to expedite site selection and patient accrual, the Task Force proposes fostering clinical trial agreements for registration trials.

6. *Create a pilot program for oncology products that utilize real-world evidence.*

“Real world” evidence generated through electronic medical information is an untapped source of regulatory information. This evidence could provide important new safety information on approved drugs and insight into how the drug is being used in a post-approval setting, information that can complement data obtained through clinical trials. Capturing real world evidence could transform evidence generation, simplify the capture of data, and streamline clinical development, while reducing cost. Under this proposed pilot, FDA would hold a workshop on methods development in using real world evidence to generate clinical evidence for regulatory decision making. It is expected that this pilot could ultimately have implications for other therapeutic areas, including rare diseases. Under this proposed pilot, and consistent with proposed Prescription Drug User Fee Act VI (PDUFA VI) commitments, FDA would hold a workshop within 4 to 6 months examining potential uses of real world evidence in oncology following agreement with the agency.

7. *Strengthen the quality of intellectual property rights to invest in innovation.*

The Department of Commerce and USPTO are heavily investing in continually improving the clarity and consistency of intellectual property rights. By improving the quality and clarity of the patents issued, through efforts like the recently launched Enhanced Patent Quality Initiative, USPTO can increase the market’s confidence in the certainty of those intellectual property rights. Such certainty enables greater capital investment, further spurs research and development efforts, and promotes greater cross-licensing opportunities for biotechnology companies looking to invest in new patient-centered treatments by building on prior breakthrough discoveries. Moreover, such investments bring greater accuracy to patents issued, helping to curb the rate of law suits that concentrate around those sorts of patents, which may have vague claims or scant prosecution history—freeing up financial capital to be spent on innovation rather than litigation. USPTO appointed a Deputy Commissioner for Patent Quality in 2015. Beginning in 2016 and continuing into 2017, USPTO has begun implementing a series of initiatives to minimize ambiguity as to what precisely a patent for a new medical breakthrough is claiming, and to increase transparency of who owns the patent, so as to enhance licensing opportunities among companies looking to build on each other’s inventions, including therapeutic breakthroughs.

Strategic Goal 4 – Strengthen Prevention and Diagnosis

As scientists gain an increasing understanding of the causes of cancer, the public can gain cumulative benefits from the broader arsenal of tools for combatting this devastating disease. Today we know that there are effective strategies for defeating certain forms of cancer. In some cases, these strategies may require avoiding behaviors that increase our risk, while in other cases we must employ screening efforts to detect and diagnose cancer before it spreads. Cancer prevention and early detection improves life expectancy and reduces the need for costly treatments. For instance, about one-third of adults aged 50 and older—22 million people—have not been screened for colorectal cancer as recommended.

Increasing colorectal cancer screening rates to 80 percent would prevent more than 200,000 deaths in this age group by 2030.⁷

Despite the opportunities afforded by a growing knowledge base, significant barriers stand in the way of achieving the full promise of prevention. One-third of cancer deaths are still linked to smoking cigarettes. Vaccinations for human papilloma virus (HPV), a cancer-causing virus, remain low for both adolescent girls and boys. Reducing environmental exposures to known cancer-causing agents remains a challenge. The Affordable Care Act is a significant step in the right direction, including requirements for new health plans to cover recommended preventive screenings and the creation of new support for prevention interventions through the Prevention and Public Health Fund. Building on these efforts, under the Cancer Moonshot the Federal Government will continue to address barriers to cancer screening and prevention by advancing health programs and policies that reduce cancer risk. Prioritized efforts include increasing outreach and funding for effective prevention strategies, enhancing the understanding of environmental determinants of cancer, and enhancing the cancer screening continuum.

Year 1 Accomplishments and Plans

In the first year of the Cancer Moonshot, the Task Force identified and aligned several high-impact initiatives to begin to move the needle on cancer prevention. Examples of efforts launched in the first year include:

- ***Promoting HPV Vaccination as Cancer Prevention***

Under the Cancer Moonshot, CDC is advancing its efforts to promote cancer vaccines as a safe and effective strategy for combatting various types of cancers. As part of this effort, in September CDC renewed its commitment to the National HPV Vaccination Roundtable for an additional 5 years, which will include increased state-level support for this effort. The Roundtable, managed by the American Cancer Society, is tasked with bringing together immunization and cancer prevention stakeholders to provide education, outreach, and training to the public and to health care providers. The National HPV Vaccination Roundtable will be working to increase HPV vaccination rates by decreasing missed opportunities, raising awareness about the importance of vaccinating males and females ages 11-12, and maximizing access to and opportunities for vaccination.

- ***Partnership to Avoid Carcinogenic Risks by Reducing Radon Exposure***

Radon is the second leading cause of lung cancer and the leading environmental cause of cancer mortality in the United States. Under the Cancer Moonshot, the EPA is partnering with American Lung Association, HHS, the Department of Housing and Urban Development (HUD), and several industry and health advocacy organizations to significantly reduce radon-induced lung cancer and ensure that radon testing and mitigation, along with radon-resistant construction, are embedded within public policies and across industry practices. With the added momentum of the Cancer Moonshot, the National Radon Action Plan has a goal to reduce radon in 5 million homes and save 3,200 lives annually by 2020.⁸

⁷ Meester RGS, et al. Public health impact of achieving 80% colorectal cancer screening rates in the United States by 2018. *Cancer*, 2015; 121: 2281–2285. doi:10.1002/cncr.29336

⁸ Environmental Protection Agency. The National Radon Action Plan: A Strategy for Saving Lives.

Plans for Year 2 and Beyond

Longer-term projects for advancing efforts in improving prevention and diagnostic capabilities include: (1) increasing HPV vaccination rates by expanding efforts to support states; (2) implementing a comprehensive tobacco control framework; (3) building collaborative partnerships among federal agencies (on existing platforms and resources to investigate environmental determinants of cancer); and (4) promoting cancer screening to increase the number of Americans who are screened as recommended.

President's Cancer Panel

The President's Cancer Panel was established by the National Cancer Act in 1971 to monitor the activities of the National Cancer Program and report to the President on barriers to progress in reducing the burden of cancer. Comprising distinguished members of the scientific and public communities, the panel works to develop actionable solutions in the fight against cancer.

In recent years, the Panel energized efforts in HPV prevention by recommending a multipronged strategy for accelerating vaccine uptake in the United States and globally. By supporting HPV vaccination as an urgent health priority, the U.S. National Cancer Program has an opportunity to contribute to the prevention of millions of avoidable cancers in men and women worldwide.⁹

1. *Improve HPV vaccination rates in the United States.*

Every year, more than 30,000 HPV-related cancers are diagnosed,¹⁰ and only 42 percent of adolescent girls and less than 30 percent of adolescent boys have completed the recommended HPV vaccination series.¹¹ Since 2013, CDC has supported a multicomponent approach to increasing HPV vaccination coverage among U.S. adolescents, and the agency proposes to expand the current work to a larger scale. This strategy focuses on improving provider practices in HPV vaccination as well as increasing public awareness about the benefits of the vaccine and risks associated with HPV-related diseases. This strategy includes: (1) developing a jurisdiction-wide joint initiative with immunization and cancer stakeholders; (2) launching a comprehensive communication campaign targeted at parents; (3) implementing strategies to improve provider practices including Immunization Information System (IIS)-based reminder/recall for adolescents aged 11-18 years; (4) using assessment and feedback to evaluate and improve the performance of immunization providers in administering the HPV vaccine series consistent with current Advisory Committee on Immunization Practices recommendations; and (5) executing communications strategies targeted to immunization providers.

CDC will work with its Immunization and Comprehensive Cancer Control program awardees and national organizations to implement this multicomponent strategy at the national, state, and provider levels. The agency will provide funding and technical assistance to awardees to implement IIS-based reminder/recall and use assessment and feedback to evaluate and improve

⁹ President's Cancer Panel Annual Report 2012-2013. Accelerating HPV Vaccine Uptake: Urgency for Action to Prevent Cancer.

¹⁰ Centers for Disease Control and Prevention. How Many Cancers Are Linked with HPV Each Year?

¹¹ Reagan-Steiner S, et al. National, Regional, State, and Selected Local Area Vaccination Coverage Among Adolescents Aged 13-17 Years—United States, 2015. *MMWR Morb Mortal Wkly Rep* 2016;65:850-858. DOI: <http://www.cdc.gov/mmwr/volumes/65/wr/mm6533a4.htm>

the performance of immunization providers in administering the HPV vaccine series. The National Comprehensive Cancer Control Program (NCCCP) will work with the Immunization awardees and national partners to provide support for the development and implementation of jurisdiction-wide plans through its state, tribal, and territorial program awardees. CDC's health communicators and its public health partners will develop a national public campaign to promote HPV vaccination and develop targeted communications strategies to improve provider practices related to HPV vaccination. Also, of note, NCI will continue to conduct randomized control trials on two- and single-dose vaccination protocols, which will potentially affect HPV vaccination efforts internationally. In addition to ongoing technical assistance provided to states for reporting on this measure, the Centers for Medicare & Medicaid Services (CMS)—in partnership with CDC and the Health Resources and Services Administration (HRSA)—will launch an HPV Vaccination State Affinity Group to support states in the development and/or implementation of strategies to improve uptake of HPV vaccine.

2. *Implement smoking cessation strategies across the Medicaid population.*

By dramatically increasing the use of smoking cessation treatments among Medicaid enrollees, Massachusetts reduced smoking prevalence in this high-risk population from 38 percent to 28 percent over a 2.5-year period, with improvements in health outcomes and health care cost reductions.¹² Tobacco priorities within CDC's "6/18" initiative include increasing Medicaid enrollees' access to and use of evidence-based tobacco cessation treatments in order to reduce tobacco use in this population. CMS and CDC will further explore activities to support states in replicating the success in Massachusetts by working together to address coverage, awareness, and operational barriers to smoking cessation. Specifically, these include efforts by state Medicaid and tobacco control programs to: (1) remove barriers to accessing Medicaid cessation coverage, including copayment; (2) promote use of these services to Medicaid enrollees and health care providers; (3) support provider quality improvement programs to ensure the sustained delivery of high-quality smoking cessation services; (4) enhance quitline services to support quit attempts by providing robust counseling and initial distribution of cessation medications while reducing physician/health system burden; and (5) assess the effectiveness of these interventions.

3. *Screen environmental chemicals through high-throughput in vitro assays.*

The 2008-2009 Annual Report of the President's Cancer Panel concluded that the "true burden of environmentally induced cancer has been grossly underestimated." To better identify environmental chemicals that may pose human health risks, EPA, the National Institute of Environmental Health Sciences National Toxicology Program, the National Center for Advancing Translational Sciences, and FDA formed the Toxicology Testing in the 21st Century (Tox21) consortium in 2008 to use quantitative high-throughput screening methods to test thousands of chemicals across dozen of *in vitro* assays representing known toxicity pathways. A complementary effort by EPA, Toxicity ForeCaster (ToxCast), has tested fewer chemicals across a greater number of assays. A subset of the Tox21 and ToxCast high-throughput screening assays have been mapped to the 10 key characteristics of carcinogens developed by the International Agency for Research on Cancer to support chemical hazard assessment. The Tox21 consortium

¹² Massachusetts Department of Public Health, Fiscal Year 2009. Massachusetts Tobacco Cessation and Prevention Program Annual Report.

will work to develop an expanded suite of high-throughput *in vitro* assays that fill current assay gaps and more comprehensively cover the 10 key characteristics. Using robotic technology, the consortium will screen the entire Tox21 chemical library of approximately 10,000 environmental, industrial, pesticidal, and food-additive chemicals in concentration response across the expanded assay set to identify chemicals that may possess previously unknown carcinogenic characteristics or that may be acting through multiple characteristics to produce synergies in environmental carcinogenesis.

4. *Expand colorectal cancer screening efforts in the United States.*

CDC currently funds the NCCCP to support comprehensive cancer control across the United States. The NCCCP convenes state-level stakeholder coalitions to leverage resources to prevent and control cancer. All NCCCP programs have made access to colorectal cancer screening a priority and are supporting the National Colorectal Cancer Roundtable's (NCCRT) "80% by 2018" initiative to increase colorectal cancer screening rates of eligible adults to 80 percent by 2018. State coalitions are critical to the success of the initiative because they are uniquely positioned to convene the appropriate stakeholders (e.g., health care providers, health systems, communities, businesses, community health centers, state and local government, survivors, and others), build appropriate momentum, and generate collective support in every state and several tribes and U.S. territories.

Earlier this year, NCCCP, in partnership with the American Cancer Society, NCCRT, NCI, HRSA, and other colorectal cancer stakeholders, coordinated an inaugural training with 11 state teams to solidify action to improve colorectal cancer screening rates. Participants developed specific state and jurisdiction plans to increase screening rates. Moving forward, CDC is planning two additional state team training forums in Fiscal Year 2017. CDC will continue to leverage partnerships to expand its reach to realize the ambitious national colorectal cancer screening goals proposed by Healthy People 2020, the National Prevention Strategy, and other initiatives, such as the National Colorectal Roundtable's "80% by 2018" Initiative.

5. *Remove barriers that limit access to colorectal cancer screening.*

Under the Affordable Care Act, a screening colonoscopy is required to be performed without co-payments or co-insurance for adults over 50. For Medicare beneficiaries, however, if a tissue biopsy or polypectomy is done during the procedure, then co-payments and/or coinsurance are required. The President's Fiscal Year 2017 budget proposes legislation to waive co-payments when polyps are removed during screening colonoscopy. Moving forward, CMS will provide technical assistance as needed as Congress considers legislation.

Strategic Goal 5 – Improve Patient Access and Care

For patients to be successful in the fight against cancer, they must have access to resources and support throughout their cancer journey. Cutting-edge cancer diagnostics and treatments must be disseminated rapidly and equitably, and today's technologies can help make this a reality. However, the challenges facing patients with cancer can be overwhelming and feel insurmountable, and the journey does not end despite the word "remission." Many patients have pressing health needs that they have not been able to address because, without insurance coverage, they could not afford to see a doctor or obtain necessary medications.

The Affordable Care Act has opened the door to health coverage for millions of people who may never have had insurance before or who may have been uninsured for a long time. With increased health care coverage as the foundation, the Task Force scanned the current health care landscape for short- and long-term opportunities with the greatest potential for meaningful impacts for patients. Throughout this analysis, the Task Force identified opportunities to improve efficiencies of existing programs; expand or extend current efforts through patient and clinician education, outreach, and technology; and translate knowledge into workable policies to improve cancer prevention, detection, and quality of care. Additionally, the Task Force remains committed to finding new ways of ensuring each and every patient receives quality care during treatment and survivorship.

Year 1 Accomplishments and Plans

Our most significant challenges will come from the need to work across different federal departments and agencies with distinct missions and authorities, and across levels of government (e.g., federal, state) with differing mandates and constraints. Funding and resource limitations are an ongoing challenge. Nonetheless, the vision is to improve existing programs so that they work optimally, efficiently, and with a broader perspective on their opportunities to improve health care quality and the health of people with and at risk of cancer. Efforts launched in Year 1 include:

- ***Improving Patient Access to Medications and Information***

FDA is scaling up its efforts to provide accessible and timesaving information for physicians and patients pursuing expanded access requests for investigational drug treatments in cases of serious or life-threatening conditions. Most recently the agency published three new guidance documents, including one focused on reducing the time it takes for physicians to make expanded access requests. To further these actions, the agency is accelerating its efforts, including discussions with external parties, to serve as a connection point between patients, providers, and drug developers to facilitate expanded access requests.

- ***New Federal Incentives for Coordinated Cancer Care***

CMS announced the enrollment of nearly 200 participating physician practices including more than 3,200 oncologists in its Oncology Care Model, a multi-payer model focused on incentivizing high-quality, high-value, patient-focused cancer care. Participants constitute a geographically, clinically, and organizationally diverse group of practices providing roughly \$6 billion in care for an estimated 155,000 beneficiaries per year during the 5-year model who have committed to providing enhanced services to Medicare beneficiaries such as care coordination and navigation. These practices also agree to use national treatment guidelines for care and CMS will supply practice feedback data for continuous care improvement.

- ***Improving Cancer Survivorship through Art***

The National Endowment for the Arts (NEA) is designing a pilot project with members of its network of State Art Agency partners to develop art programs within designated cancer centers and health facilities at the state level. Building on its successful work in using the arts to create therapeutic activities for military members, Veterans, youth, and aging populations, the NEA along with its state partners anticipate that this pilot will demonstrate the efficacy and benefits of therapeutic arts activities for cancer patients and survivors.

Plans for Year 2 and Beyond

In the first year of its efforts, the Task Force aimed to make significant progress in strengthening working relationships with relevant departments and agencies, and began the process of detailing deliverables described below. Near- and long-term priorities include:

1. *Identify and implement culturally and linguistically appropriate cancer education and outreach efforts.*

Work across CMS, CDC, HRSA, and state Medicaid agencies will support efforts to build relationships with underserved communities to foster productive communication with eligible groups that have not purchased health insurance. Such efforts will lay the groundwork for most effectively encouraging eligible people to enroll. Federal partners will conduct focus groups and listening sessions with under-enrolled groups to identify outreach needs in order to improve uptake of cancer prevention and screening services (including smoking cessation and HPV vaccination efforts), and clinical cancer management services. These sessions will inform the development of educational materials and messaging for public audiences that emphasize the importance of cancer screening tests, and provide information about treatment options, including the availability of clinical trials. All education and outreach initiatives should be designed and disseminated in a culturally and linguistically appropriate manner with emphasis on addressing cancer disparities in various populations. VA will develop tools for integration into the EHR to help clinicians synthesize elements of a patient's care into a survivorship care plan that can be further individualized by the clinician before being given to the patient, communicated to other clinicians participating in the patient's post-treatment care, and to serve as the backbone for task tracking to implement the plan.

2. *Require expedited coverage decisions for patients with a cancer diagnosis in the VA system.*

For Veterans who are new to the VA and who have a cancer diagnosis, VA will work to create more seamless processes for eligibility screening and enrollment into VA care. For both new and known VA patients with cancer, VA will aim to implement direct scheduling by the Veteran into oncology care so that any unnecessary delays associated with requiring a primary care physician to authorize the specialty referral can be eliminated.

3. *Comprehensively identify cancer survivorship issues and develop solutions to improve health outcomes for cancer survivors.*

The medical, psychosocial, and economic challenges facing cancer survivors are an increasingly important and complex set of issues, especially as more Americans survive cancer diagnosis and treatment. NCI estimates that there are currently 14.5 million cancer survivors in the United States. Although a body of research exists on this topic, more work remains to be done to comprehensively identify survivorship problems and solutions, and to translate those solutions into effective policies. Under the Task Force's leadership, federal agencies, including CMS, VA, DoD, CDC, and NIH, will engage in a series of efforts related to addressing survivorship challenges. Initial priorities include hosting a summit on the topic of cancer survivorship, with follow-up activities focused on developing a framework for addressing the medical, psychosocial, and economic challenges encountered by cancer survivors and integrating relevant elements of this framework into EHR standards.

4. *Map cancer service delivery and care across the Nation.*

Mapping the current state of cancer service delivery is foundational for developing strategies to improve the health of the U.S. population and enhance care for all those suffering from cancer. CMS and CDC in collaboration with other partners are working together to identify ways in which cancer screening and prevention services, along with care delivery, can be tracked and assessed across the Nation, and to further identify disparities across communities and regions.

One example is the CMS Office of Minority Health Mapping Medicare Disparities tool, which can be modified to map disease prevalence nationally and regionally by race, sex, and other demographic characteristics. In addition to mapping disease prevalence and health care service delivery, it is noteworthy that quality reporting programs exist across care settings from the physician's office to post-acute to long-term care facilities. CMS will be repackaging existing quality products pertinent to cancer screening and management for ease of use for health care providers, as well as delineating quality measure gaps that can inform future quality measure development. These activities will occur on an ongoing basis over the 2017-2019 period and beyond.

5. *Improve access to care by leveraging technology such as virtual networks.*

Federal efforts are currently underway to capitalize on advances in virtual technology that are being developed and implemented across the Nation. These efforts include use of these solutions to facilitate entry into health care, improving continuity of care plan implementation, expanding provider training, and improving the quality of health information for decision making, to mention a few.

The Medicare and Medicaid programs, as well as the VA, are exploring the use of technology and virtual solutions to increase access to care, particularly in rural areas. For example, Medicaid allows states the option of covering a broad range of telehealth services and most states use telehealth in their Medicaid programs. Additionally, the national expansion of such bundled payment models (and their included waivers) may be a potential solution to barriers to care in general, and may help to mitigate care fragmentation generally, enabling better care coordination across cancer and general health care for patients. CMS has begun to explore the feasibility of applying virtual technical solutions to address transportation and other issues that may affect access to high quality cancer care. Some worthy of mention include care that is guided through virtual consultation (e.g., Project ECHO, VA).

VA has long been a leader in telemedicine, providing more than 2,140,000 telehealth episodes of care last year to more than 677,000 patients in more than 45 specialty areas. For example, VA has a centralized genetic counseling service that currently reaches 80 of the 152 VA medical centers and clinics. Veterans are engaged using the VA's telehealth system, generally with a synchronous audio-visual session. This service will continue to expand to allow genetic counseling to be provided as Veterans with germline cancer susceptibility syndromes are identified through the VA's Precision Oncology Program.

VA is identifying and scaling best practices in virtual cancer care delivery through its "Diffusion of Excellence" initiative. Virtual Cancer Centers will enhance the cancer care experience of Veterans by providing an Oncology Patient Aligned Care Team medical home model that facilitates communication and coordination of care. Services are delivered through virtual tumor boards, electronic consultations, and telemedicine directly to patients. In virtual tumor boards,

experts for each type of tumor provide guidance on clinical pathways for patient care and meet regularly for virtual discussions of individual Veterans' cases. Care plans are iteratively implemented, measured, and improved through implementation science, learning health care, and precision oncology. Patients who have been evaluated by virtual tumor boards have been able to start treatment much faster than those who have not had such an evaluation.

Moving forward, in consultation with CMS and VA, these efforts could be augmented by funding additional networks, targeting specific cancer-relevant areas, or enhancing capabilities and reach of current networks.

Reaching Target: Ending Cancer as We Know It

Taken together, these current efforts and future plans signify an initial down payment for accelerating gains in preventing, diagnosing, and treating cancer—that is, aiming to achieve 10 years of progress in half the time. Ultimately, through the creation of new paradigms for generating, sharing, and integrating research and clinical data to enhance patient care, the Cancer Moonshot can accelerate the delivery of effective cancer prevention strategies, diagnostics, and treatments to patients in communities around the world. The effort isn't about scientific research or technology development; it isn't about computational power or capability; it isn't about health care records management—these are simply the innovative strategies and tools we now have to deploy in the fight against cancer. The Cancer Moonshot is about the entire cancer ecosystem working together to use our resources and tools intelligently and aggressively to catalyze improvements in care and our understanding of cancer.

This is the “moonshot” for our time. In 1961, President Kennedy called on the Nation to “commit itself to achieving the goal, before this decade is out, of landing a man on the moon and returning him safely to the Earth.” Similarly, President Obama and Vice President Biden are calling on the Nation, and the world, to unite around a common mission—to harness our vast scientific and technological capabilities to dramatically change the incidence of cancer and the experience and outcomes of cancer for patients, keeping the needs of patients at the center of it all. Together, we can end cancer as we know it.

C





THE CANCER MOONSHOT BLUE RIBBON PANEL REPORT AT A GLANCE



“ I plan to do two things: 1) Increase resources—both private and public — to fight cancer. 2) Break down silos and bring all the cancer fighters together—to work together, share information, and end cancer as we know it. And the goal of this initiative is simple—to double the rate of progress. To make a decade’s worth of advances in 5 years. ”

Vice President Joe Biden
February 2016

In his final State of the Union address, in January 2016, President Barack Obama tasked Vice President Joe Biden with heading up a new national mission—to make a decade’s worth of advances in cancer prevention, diagnosis, treatment, and care in 5 years.

The Cancer Moonshot is the coming together of science, technology, advocacy, social science, and big data to solve cancer’s greatest challenges.

Cancer is a complex disease that must be attacked on many fronts—through accelerating the best science and by breaking down administrative and financial barriers, increasing data sharing across all research sectors, and enhancing collaboration between the public and private sectors.

Since its launch, the Cancer Moonshot has brought diverse communities together to contribute their ideas and expertise for fast tracking progress against cancer.

Providing the Research Blueprint

To guide the scientific direction for the Cancer Moonshot, the Administration established a Blue Ribbon Panel of many of the nation’s top cancer experts—cancer researchers, oncologists, patient advocates, and private-sector leaders—to give careful thought to what could be done to expedite progress against cancer.

After just a few short months, the Blue Ribbon Panel delivered a report which summarizes the work of the Panel and its working groups into 10 transformative recommendations to shape the research blueprint for the Cancer Moonshot.

10 Years of Progress in 5: Blue Ribbon Panel Recommendations

THE BLUE RIBBON PANEL'S RECOMMENDATIONS FOR ACCELERATING PROGRESS AGAINST CANCER

A. Establish a network for direct patient involvement in cancer research

Cancer clinical trials offer patients the opportunity to directly engage in cancer research and receive potentially promising treatments. But trials can be hard for patients to find and enroll in. This recommendation calls for cancer patients to join a new national network that, with appropriate privacy safeguards, will provide them with a genetic profile of their own cancer and let them "pre-register" for clinical trials, so they can be contacted when a trial for which they may be eligible opens. Researchers will be able to access patient outcomes reported in the network database to conduct studies into what treatments work, in whom and in which types of cancer.

B. Create a clinical trials network devoted exclusively to immunotherapy

Unleashing a patient's own immune system to attack cancer is transforming cancer treatment. But understanding why these promising immunotherapies work in only some patients will take intensive research before more patients can benefit. Establishing clinical trials networks devoted exclusively to immunotherapies for pediatric and adult cancers would advance research in this area and could lead to new vaccines to prevent cancers of all types in children and adults.

C. Develop ways to overcome resistance to therapy

A major cause of cancer death is drug resistance, when treatments that are effective initially lose their ability to control the disease. This recommendation calls for establishment of multidisciplinary research teams to understand the details of how drug resistance develops and find ways to prevent tumors from resisting the drugs meant to kill them.

D. Build a national cancer data ecosystem

Technology has enabled the collection of a massive amount of patient data. But these data are often stored in proprietary databases or accessible only to a select group of people, limiting their usefulness as a research resource. A national ecosystem that links many of the nation's largest data repositories would enable one-stop, free access for researchers, doctors, and patients to share data on cancer and fuel faster progress.

E. Intensify research on the major drivers of childhood cancers

Researchers have learned that one of the major drivers of pediatric cancers are rogue proteins, known as fusion oncoproteins. Better understanding of how these proteins function is critical for advancing progress against pediatric cancers. Intensifying research in cell biology, genomics, proteomics, and drug development would accelerate development of new therapies that target these cancer-causing proteins.

F. Minimize cancer treatment's debilitating side effects

The side effects of cancer and its treatment can be excruciating for patients, particularly for children, with the impact on their developing bodies too often causing long-term health problems. This recommendation calls for research to support development of guidelines for managing patient-reported symptoms and side effects of cancer treatment in adults and children, with the goal of helping patients stay on their drug regimens and improve their quality of life.

G. Expand use of proven cancer prevention and early detection strategies

Several cancer prevention and risk reduction strategies have proven to be highly effective, including tobacco control, colorectal cancer screening, and the HPV vaccine. Boosting prevention research to identify ways to increase uptake of these strategies, especially in medically underserved populations could greatly reduce incidence and death from lung and other tobacco-related cancers, colorectal cancer, and cervical and other HPV-related cancers, respectively. The recommendation also calls for increasing testing for hereditary cancer syndromes in people with certain types of cancer and their family members so those identified as high risk can begin early prevention or screening efforts.

H. Mine past patient data to predict future patient outcomes

Understanding why some patients with the same type and stage of cancer, and same treatment, may end up with very different outcomes continues to be an important research challenge. Analysis of existing tumor tissue from patients who received standard of care treatment, stored at biobanks around the country, may enable researchers to discover genetic and other factors that distinguish which individuals would benefit from standard care versus experimental treatment in a clinical trial.

I. Develop a 3D cancer atlas

Oncologists today rely on past experience, consultation with multidisciplinary teams, published studies, and other sources to make

diagnosis and treatment decisions. Providing a web-based catalog of the genetic lesions and cellular interactions in tumor, immune and other cells in the tumor microenvironment and one that maps the evolution of tumors –from development to metastasis –will enable researchers to develop predictive models of tumor progression and response to treatment that will ultimately help oncologists make informed treatment decisions for each patient.

J. Develop new cancer technologies

Under this recommendation, increased collaboration among the public and private sectors to develop new tools or refine technologies that are showing remarkable promise – including implantable microdosing devices that deliver drugs directly into a tumor to test their effectiveness, and advanced imaging technologies to study cancers at extremely high resolution – would help doctors deliver smarter, more effective therapies to patients.

When implemented, the Blue Ribbon Panel's 10 recommendations are poised to advance critical areas of research to prevent and treat cancer and to meet the goals of the Cancer Moonshot and the hopes of cancer patients and their loved ones.

Taken together, these recommendations create a vision for the future of cancer research and treatment in which:

- Patients contribute their cancer data, obtain a genomic profile about their tumor, learn about what treatments might work best given their profile, and find other relevant information, including clinical trials that may be appropriate for them.
- Doctors have access to information that better predicts treatment outcomes and helps control their patients' symptoms and side effects.
- Researchers can identify possible targets for the development of new cancer treatments and preventive interventions, including immunotherapies, as well as learn more about how to avoid or counter cancer drug resistance in patients.

For the Blue Ribbon Panel Report visit cancer.gov/brp

**VICE
PRESIDENT
JOE BIDEN**

"This is our moonshot.

I know that we can help solidify a genuine global commitment to end cancer as we know it today –and inspire a new generation of scientists to pursue new discoveries and the bounds of human endeavor."

Back from the OVAL
10/17/16

EVENT MEMO

THE WHITE HOUSE

Washington

OCTOBER 17, 2016

Meeting with Artist Robert McCurdy

DATE: October 17, 2016

LOCATION: Oval Office

TIME: 3:15pm - 3:45pm

FROM: Melissa Winter and Bill Allman

I. PURPOSE:

This meeting marks the fifth meeting with a potential portraitist for either **YOUR** official White House portrait or the portrait which is commissioned by the National Portrait Gallery.

Thus far into the process, **YOU** and the First Lady have met with artists Barkley Hendricks, Dean Mitchell, Sharon Sprung, and Amy Sherald. FLOTUS has indicated an interest in moving forward with Amy Sherald for the NPG portrait and Sharon Sprung for the White House portrait.

We will be scheduling a meeting in the coming weeks with the final candidate Kehinde Wiley. He is currently out of the country.

II. SEQUENCE OF EVENTS:

YOU will meet with artist Robert McCurdy for 30 minutes

III. PARTICIPANTS:

YOU

Bill Allman, White House Curator

Melissa Winter

*Thelma Golden is unable to attend

IV. BIOGRAPHY:

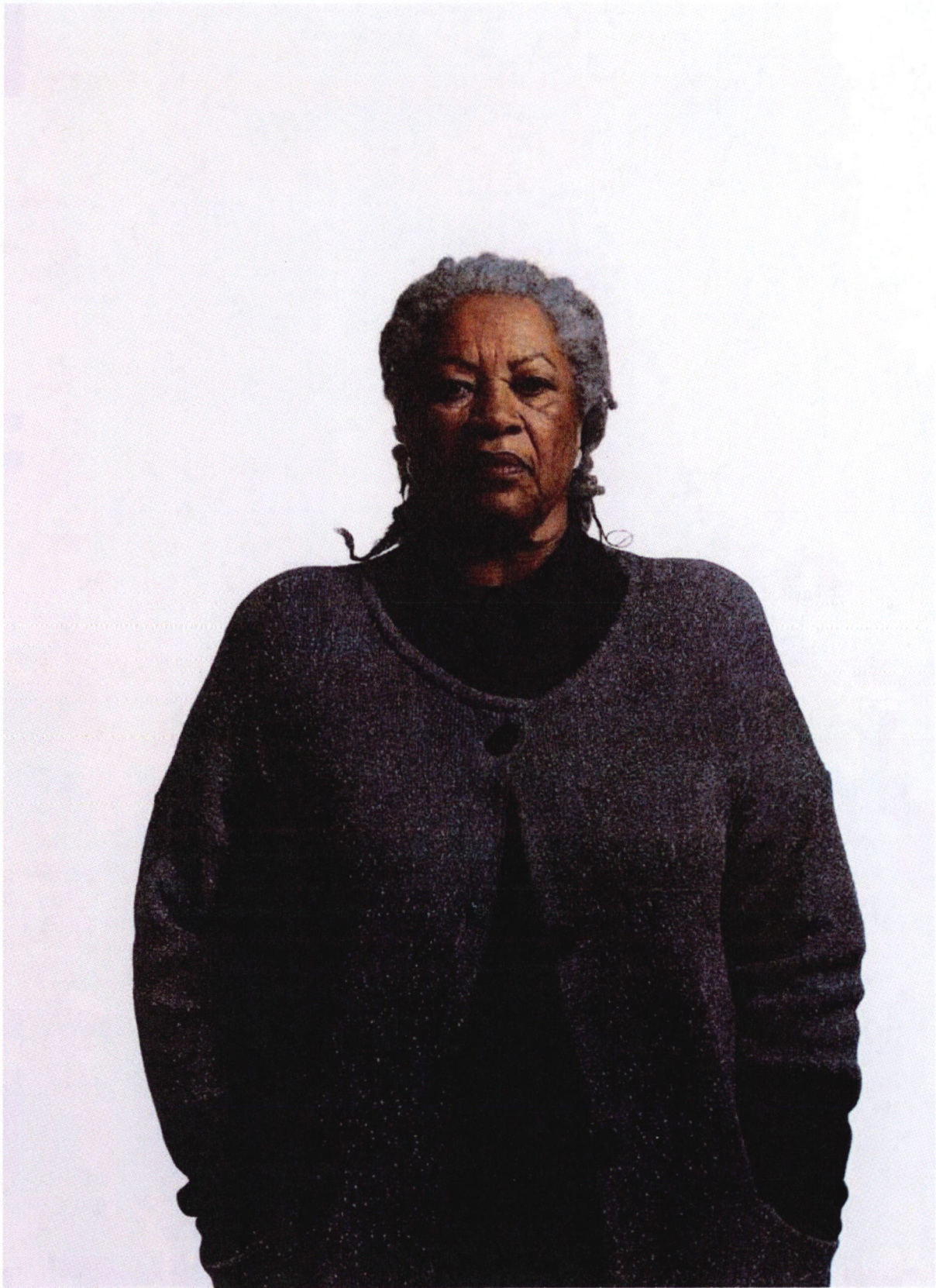
Robert McCurdy



Robert McCurdy, age 64 and a Pennsylvania native, has been exhibiting his photography and paintings for the past thirty years. McCurdy begins his painted portraits with a photograph, asking his sitters to address the unseen viewer directly and to make no gestures. McCurdy's goal is to provide a neutral environment in order to maximize the highly personal nature of the encounter between subject and viewer.

McCurdy has been working on a series of *Portraits* depicting notable personalities such as His Holiness the Dalai Lama, Gabriel Garcia Marquez, Toni Morrison, and Nelson Mandela. McCurdy attained his BFA at the Maryland

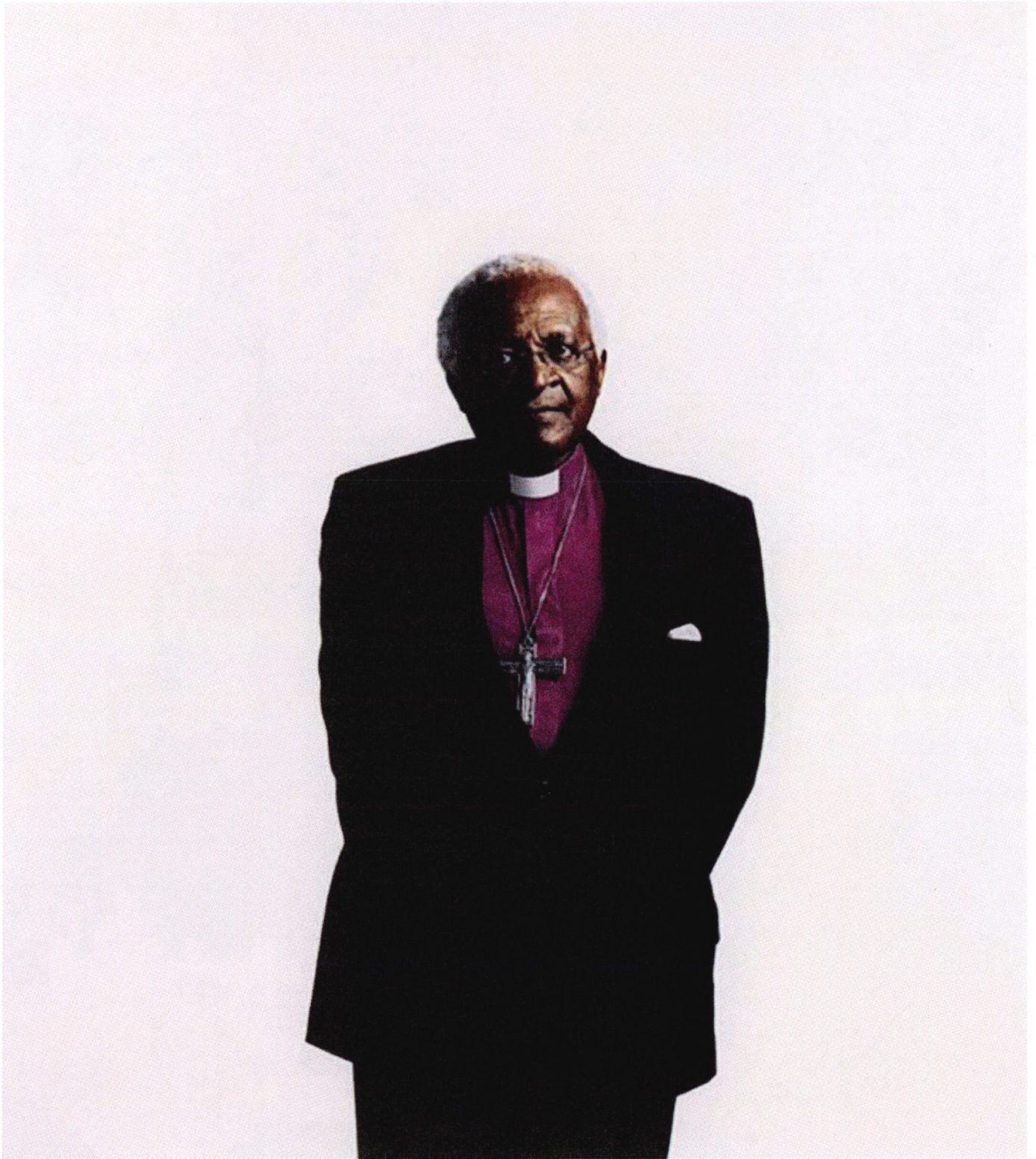
Institute College of Art, and received an Arts Fellowship from Yale University. He has previously shown in galleries across the nation including the National Portrait Gallery.



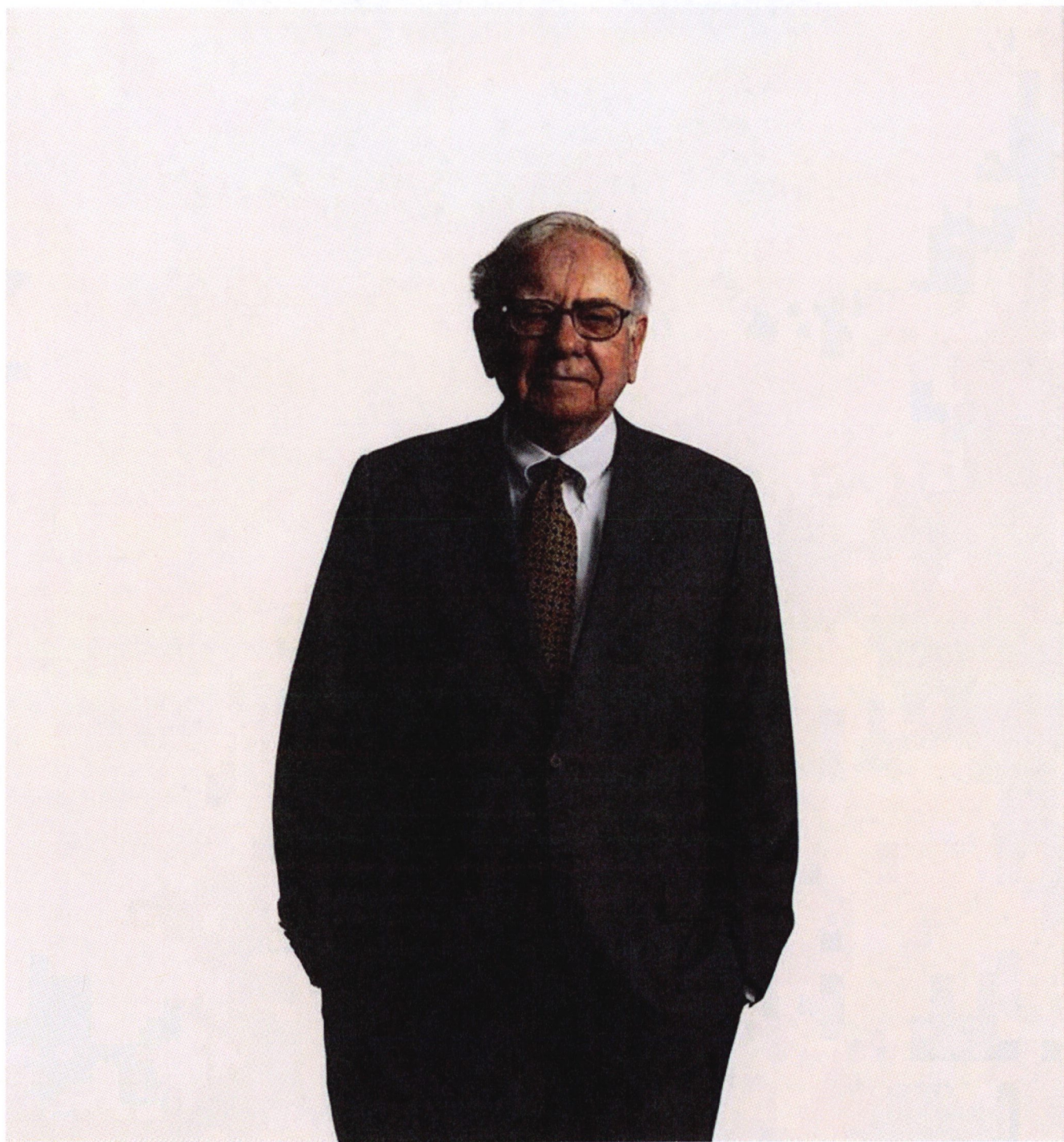
Robert McCurdy,
Untitled (Toni Morrison), Oil on canvas, 73 x 68 in, 2006 (on loan at the National Portrait Gallery)



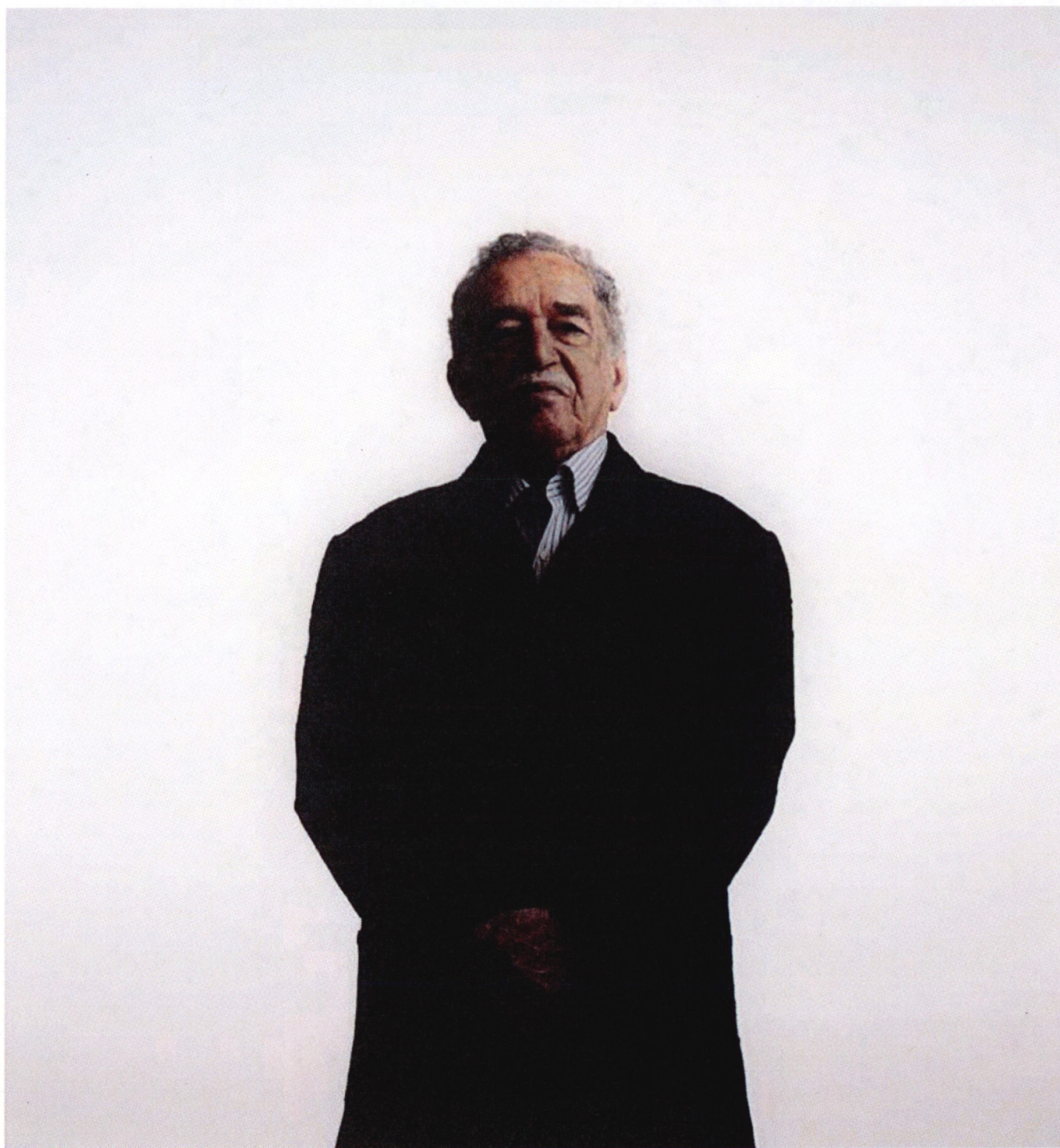
Robert McCurdy
Untitled (Nelson Mandela), Oil on canvas, 72 x 68 in, 2009



Robert McCurdy
Untitled (Bishop Desmond Tutu), Oil on canvas, 73 x 68 in, 2010



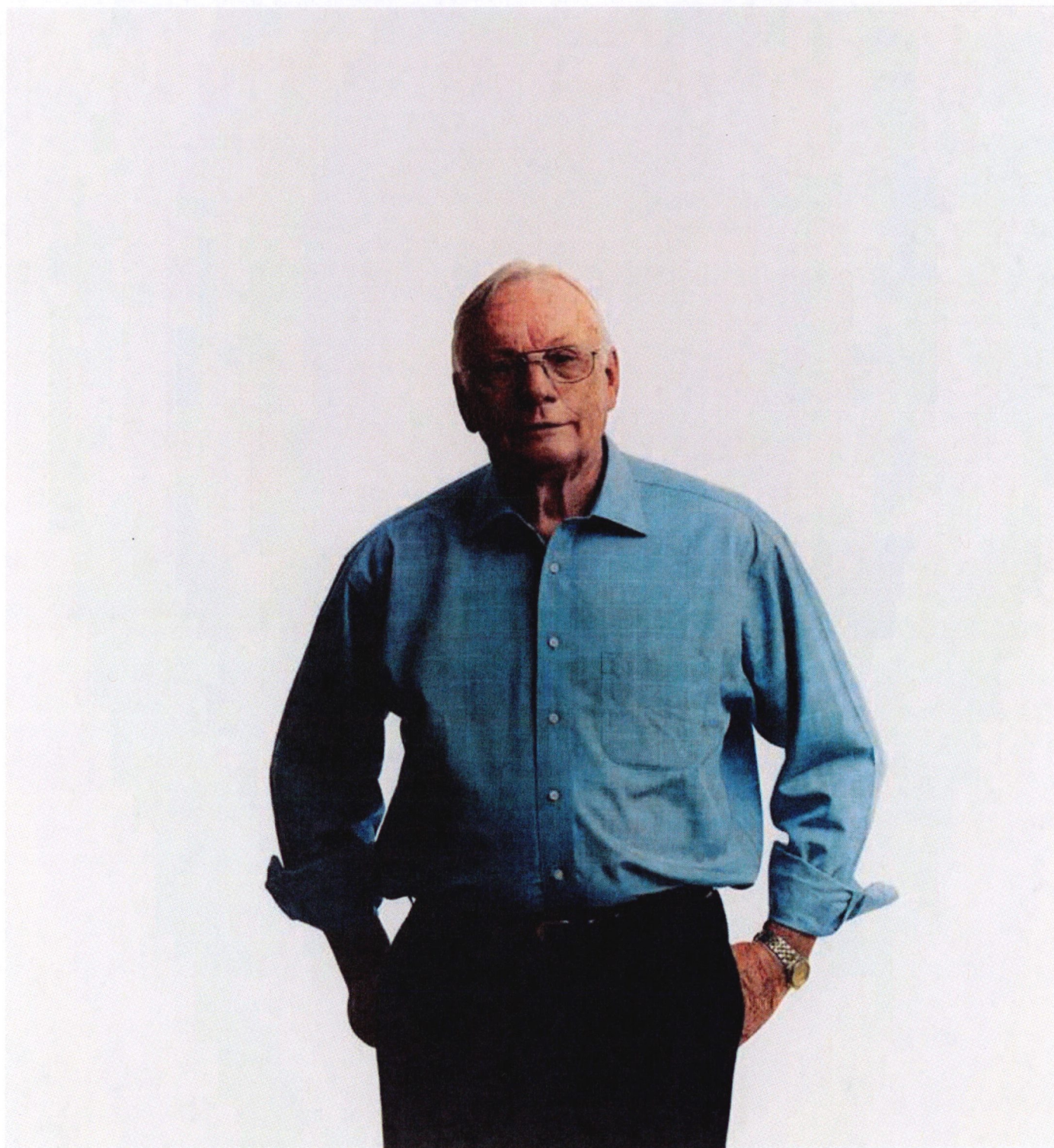
Robert McCurdy
Untitled (Warren Buffett), Oil on canvas, 73 x 68 in, 2013



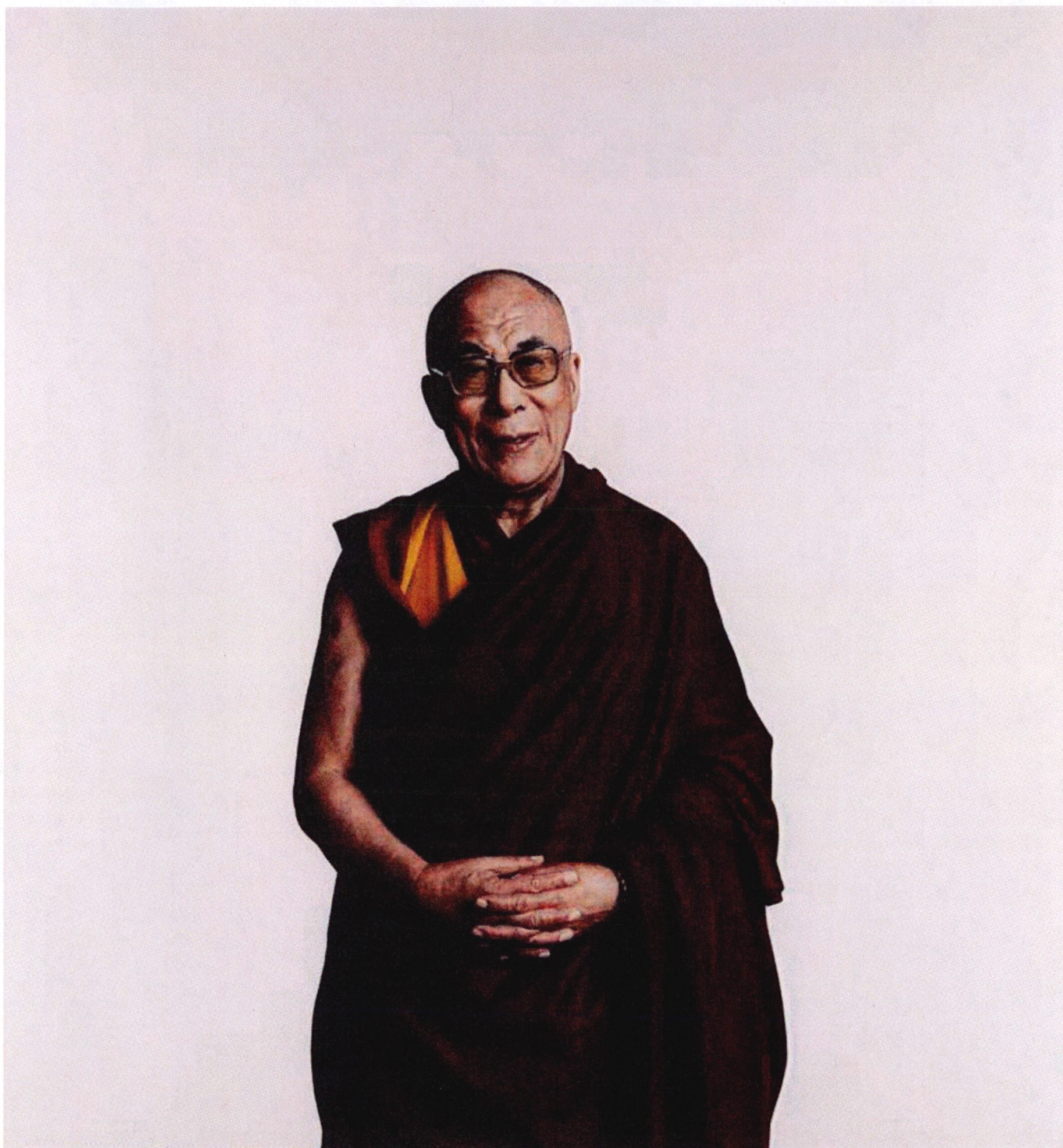
Robert McCurdy
Untitled (Gabriel García Márquez), Oil on canvas, 73 x 68 in, 2007



Robert McCurdy
Untitled, Oil on canvas, 63 x 48 in, 1997



Robert McCurdy
Untitled (Neil Armstrong), Oil on canvas, 73 x 68 in, 2012



Robert McCurdy
Untitled (Dalai Lama), Oil on canvas, 73 x 68 in, 2008