

# Duke

**MARGOLIS CENTER**  
*for* **Health Policy**



2015-16  
Annual Report



# From the Director

Dear Friends and Colleagues,

As a start-up, the Duke-Margolis Center for Health Policy has built momentum and achieved several key milestones. Thanks to the vision of Duke University leadership, the generosity of Robert and Lisa Margolis, the scholarship of our faculty and staff, and the support of partners across Duke and beyond, our mission of improving health and health care by developing and implementing effective policy solutions rests on a solid foundation of intellectual rigor and multidisciplinary collaboration.

Dr. Margolis built a business that did well by seeking better ways to do the right thing for patients, informed by the training program at Duke University where he received leading-edge clinical education that was combined with a real commitment to teamwork and caring for people. This commitment informs our approach to health policy research and implementation that seeks to align how we deliver, pay for, regulate, and support innovation in healthcare. It also informs how we educate future leaders to take a broad, multidisciplinary perspective on health policy.

In our initial start-up phase, we worked with colleagues across Duke to create a strategic plan with three elements: improving policy support for innovations in healthcare delivery and payment that drive high quality care at a sustainable cost; supporting policy in biomedical innovation that gets needed therapies into the hands of patients while improving how we monitor and address patient safety; and piloting programs to enable current and emerging leaders to work across disciplines to improve health and health care locally, nationally, and globally. We urgently need to find and implement more effective health policies, and Duke-Margolis is committed to working across stakeholder groups and with policymakers, industry, providers, and patient advocates to formulate, test, and evaluate solutions.

We have recruited a distinguished advisory board to help us think critically about our approach and provide advice in the many areas where our board members have established expertise. We have reached out to Duke's outstanding faculty to establish collaborations and create the infrastructure that will allow us to analyze which policy approaches have the most sustainable impact on measures of value, quality, and health outcomes.

While we can't capture everything we accomplished this year in a single document, our start-up phase is already showing some accomplishments – highlighted later in this report. I hope you enjoy reading our story.

Thank you for your support,

A handwritten signature in dark ink, appearing to read "Mark B. McClellan". The signature is fluid and cursive, with a long horizontal line extending to the right.

Mark B. McClellan, MD, PhD

Director and Robert J. Margolis, MD, Professor of Business, Medicine and Health Policy

# From the Founder

Dear Friends and Colleagues,

I am delighted that you are interested in the Duke-Margolis Center for Health Policy. The team, both in Durham and at Duke in Washington, DC, has made our first year both productive and memorable.

Today's healthcare and policy challenges require that we put the very best and brightest minds to work on the big issues facing our communities, states, nation, and our interconnected global society. Health care is complicated, and it is easy to formulate solutions that have unintended and undesirable consequences affecting providers, patients, and those who care for them.

Duke University is an ideal focal point for solving the complex, difficult problems that place obstacles in the way of better health. The broad expertise at our world-class university across the arts and sciences, social sciences, and policy, combined with Duke Health's national and international leadership in clinical education, biomedical research, and patient care mean that we are able to bring together different perspectives to address these challenging health policy issues.

The expertise that exists on Duke's campus is complemented by Dr. McClellan's extensive leadership experience in policy formulation, implementation, and evaluation. Together with the outstanding team of engaged policy professionals in Washington, DC, and in collaboration with stakeholders across the healthcare community, we can take policy solutions from the mind to the marketplace and generate evidence about what really works.

We hope to make strides toward important shared goals: keeping people healthier longer, avoiding unnecessary costs through patient-centered approaches to delivering care, supporting high-value medical innovation, keeping patients safe, understanding how global innovation can inform solutions that work, and ensuring that the next generation of leaders is prepared to face challenges that we cannot even envision today.

As we close the Center's first year, Lisa and I offer our congratulations – we are excited to see what unfolds in 2017.

Sincerely,



Robert J. Margolis, MD  
Founder





# A Groundbreaking New Health Policy Center

Healthcare expenditures in the United States topped \$3.2 trillion in 2015 – a sum that is difficult to imagine. That's \$9,990 per person, making up 17.8 percent of the U.S. economy – more than any other nation in the world. And costs continue to grow.

Outstanding care is available in the United States, but are we healthier? Experts say no – the U.S. lags most developed countries in terms of life expectancy and other health measures. State-of-the-art care is out of reach for millions of people both here and abroad.

These dilemmas are why the Duke-Margolis Center for Health Policy was founded: to improve health and the value of health care by developing and implementing evidence-based policy solutions locally, nationally, and globally.

The Center began operations in January 2016. Locations in Durham, NC and Washington, DC help integrate the expertise of Duke University's scholars and academic health system with an established team experienced in convening stakeholders and conducting policy analysis. The Center is a catalyst, linking Duke's world-class research and health care with policymakers and policy analysts in the public and private sector at the local, national and global levels.

Few health policy centers have the ability to develop and integrate evidence across the spectrum from biomedical innovation to care delivery in diverse contexts. Duke-Margolis, working with partners from across Duke University and the healthcare continuum, can gather and aggregate data, use advanced analytical techniques to evaluate clinical and economic outcomes, gather input from patients, providers, and industry, detect unintended consequences, marshal evidence to support policy innovations, and test those innovations in the real world. This approach supports the so-far elusive triple aim of health care: improving the experience of care, the health of populations, and reducing the per capita cost.



## The Duke-Margolis Strategic Plan

In the first six months of 2016, Duke-Margolis completed a broad and inclusive strategic planning exercise, resulting in a plan that honors the Center's multidisciplinary design and its roots in Duke's multiple missions of education, research, and patient care.

The plan focuses on generating new knowledge, translation to real-world settings, and application of evidence to pressing policy problems in healthcare delivery, payment, and biomedical innovation.

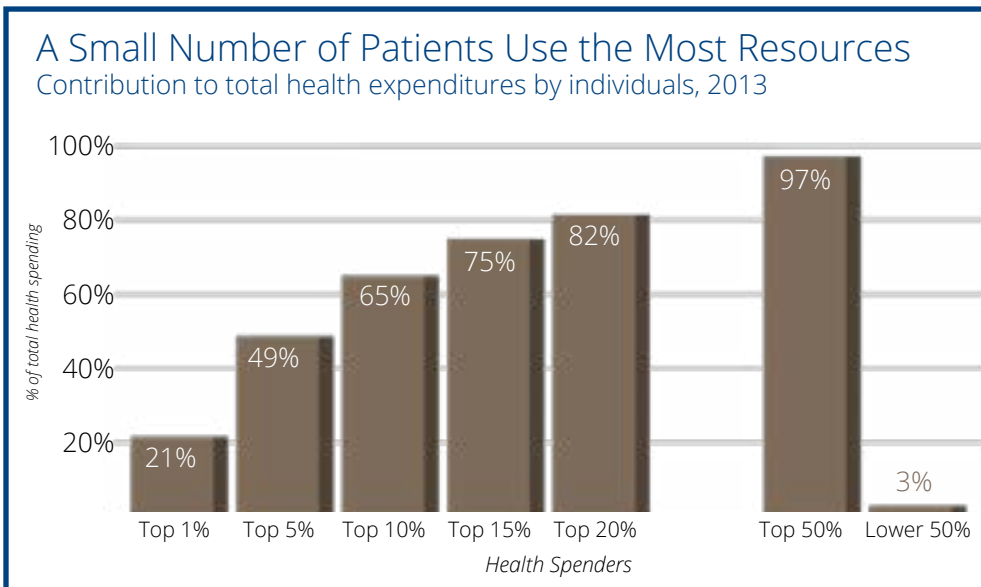
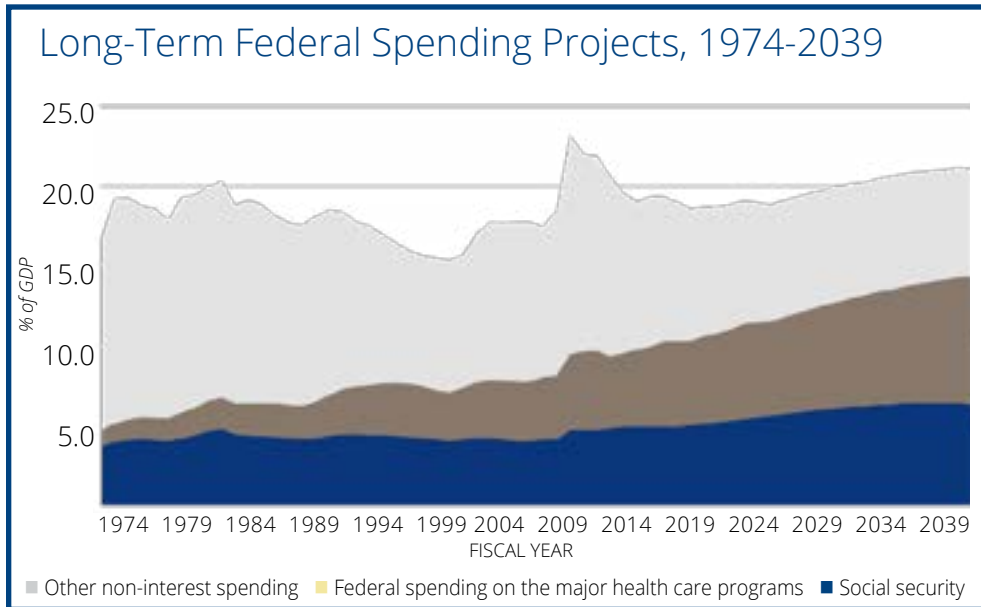
To formulate a comprehensive initial strategy and define the work we will undertake in FY 2017, the Center listened to many voices at Duke and engaged potential collaborators across the country and around the world. Through these conversations, three major themes have emerged:

- Healthcare Delivery and Payment Reform (pages 4-5)
- Biomedical Innovation and Evidence Development (pages 6-7)
- Education and Workforce Development (pages 8-9)

Work across these themes is augmented by a robust team focused on Global Health Policy (page 10), whose research and projects in countries outside the U.S. brings fresh perspectives and valuable experience to our work.

Please read on for examples of projects addressing each theme.

# U.S. Health Care Expenditures are Growing and Face Demographic Challenges



Source: Kaiser Family Foundation analysis of Medical Expenditure Panel Survey, Agency for Healthcare Research and Quality, U.S. Department of Health and Human Services

## Duke University Partners

Bass Connections

Duke-UNC U.S.D.A. Center for Behavioral Economics and Healthy Food Choice Research

Center for Health Policy and Inequalities Research

Center for Population Health Sciences

Duke Cancer Institute

Duke Clinical Research Institute

Duke Global Health Institute

Duke Population Research Institute

Innovations in Health Care

Sanford School of Public Policy

Stakeholders ranging from providers, to payers, to patients are embracing innovation toward personalized, prevention-oriented care, while facing growing pressure to address questions of cost and value. Systems are burdened by more patients with complex healthcare needs, including multiple chronic conditions requiring team-based care and coordination. Clinician burdens are increasing, with more healthcare providers reporting that they are overwhelmed by care coordination, documentation, and compliance requirements.

Recent reforms have aimed to encourage a shift away from fee-for-service to value-based payment approaches, but outcomes are still uncertain due to limited evidence on the most effective approach to reform.

Drawing on expertise from across Duke University, Duke-Margolis is focused on generating evidence that supports a shift to high-value, innovative care and empowers patients and consumers to help lead it. The projects featured below are just a few examples of our overall approach to delivery and payment reform.

## Increasing Patient and System Value With Community-based Palliative Care

A research team led by Don Taylor, PhD, MPP, and Matthew Harker, MPH, MBA, in collaboration with the Duke Clinical Research Institute and Four Seasons Compassion for Life, is testing a new model for community-based palliative care to determine if it reduces the total cost of care for Medicare while informing the development of alternative payment models that better integrate palliative care to meet the needs of patients with advanced illnesses.



Palliative care is specialized medical care that focuses on providing relief from the symptoms and stress of a serious life-limiting illness by improving quality of life for both the patient and caregivers, with or without curative treatment. Palliative care's cost-saving potential lies in coordinating care between providers in both facility-based and home settings. Better coordination can reduce expensive, unwanted, or unnecessary end-of-life care, reduce hospital readmissions, decrease emergency room visits, and enhance the quality and value of care.

Community-based palliative care is not well-reimbursed by Medicare, leading to gaps in availability. As the insurer of 8 in 10 persons who die each year in the U.S., Medicare's payment policies can have a fundamental impact on the benefits that palliative care programs provide for Medicare beneficiaries and the healthcare system. The project, which expands on a successful program across four counties in North Carolina, is also aimed at developing alternative Medicare payment models for palliative care.

Ten additional counties in North and South Carolina will benefit from interdisciplinary collaboration and integration of palliative care into the healthcare system, continuity of care across transitions from one care setting to another, and longitudinal, individualized support for patients and families. Standardized assessments and data

infrastructure facilitate quality monitoring/improvement and high-quality patient care will be evaluated to determine if they lead to decreased hospital and emergency room utilization.

*This project is funded by Grant Number 1C1CMS331331, a Health Care Innovation Award from the Department of Health and Human Services, Centers for Medicare & Medicaid Services.*

## Developing Better Evidence for More Effective and Rapid Payment Reform

With support from the Laura and John Arnold Foundation, the Duke Margolis Payment Reform Evidence Hub seeks to increase the number of evaluations of care and payment delivery models and their relevance to stakeholders. While organizations have conducted evaluations of payment reforms, they are often lengthy and costly, and the evidence they produce may be difficult to generalize or may not answer pressing policy questions.

The Hub focuses on payment reform evaluations being implemented by private payers, purchasers, and states—these are sectors where there have been few independent evaluations. Lack of confidence about the potential impact of payment reforms slows progress in improving care and lowering costs. The Hub will provide practical support expanding the breadth of evaluations; supporting greater efficiency, speed, and impact; and accelerating the dissemination of evidence.

The Hub is holding a series of public meetings and gathering stakeholder input. It has also been working collaboratively with the Health Care Payment Learning and Action Network (LAN). In its initial work, the Evidence Hub is focusing on the following activities:

- Building a clearinghouse of payment reforms (including evaluations where available)
- Identifying tools and best practices for evaluations
- Identifying approaches that could increase confidence in evaluation results

These activities will result in a series of publications and resources assessing specific gaps in evidence on payment reforms, introducing new methods to fill those gaps more efficiently, and supporting stakeholders in developing their own evidence.. The Hub will then initiate evaluations of several promising payment and delivery reforms to increase the number and quality of evaluations, their relevance and impact. The work is being led by Mark McClellan, Harvard University's Michael Chernew, and the Pacific Group's David Lansky, along with Don Taylor, Matthew Harker, Andrew Olson, and Robert Saunders. Duke University's Lesley Curtis, Director of the Center for Population Health Sciences, is a member of the Expert Working Group.

## Healthiest Cities and Counties Challenge

Duke-Margolis has partnered with the Durham County Department of Public Health and the Cabarrus Health Alliance under a planning grant from the Aetna Foundation through the Healthiest Cities and Counties Challenge.

This partnership, called the North Carolina Healthiest Counties Cross-Sector Team, will use a multi-faceted approach through several community-based programs, a longstanding Duke presence in Cabarrus County, and Duke University expertise to improve population health and health equity in Cabarrus and Durham Counties. Specifically, we



are addressing nutrition/food insecurity, physical activity, tobacco use, integrating physical activity “prescriptions” into clinical care and piloting healthcare delivery and payment reform via community health workers. In each of these major areas, we will track performance measures linked to population health and identify new steps to support them through payment reform.

Bradi Granger, PhD, FAAN, Associate Professor of Nursing, Associate Director of Duke Translational Nursing Institute, and Director of the Duke Heart Center Nursing Research Program is leading the work at Duke-Margolis.

Gayle B. Harris, MPH, RN, Public Health Director and General Manager for Well-Being and Michele Easterling, MPH, RD, LDN, Nutrition Director are leading the team at the Durham County Department of Public Health and Dr. William F. Pilkington, DPA, Chief Executive Officer and Public Health Director and Jennifer West, MS, ACSM, REACH Program Manager are leading the team at the Cabarrus Health Alliance.

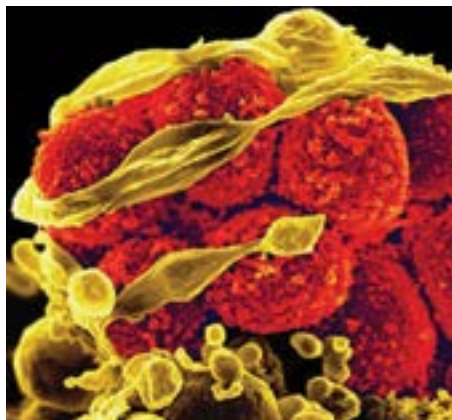


Scientific advances are driving a device, drug, and therapeutic development pipeline that includes more effective curative specialty therapies. In 2016, the U.S. Food and Drug Administration (FDA) approved 22 drugs and biologics, 36 percent of which were first in class. Nevertheless, biomedical innovation is challenged by many of the same forces driving the need to reassess delivery and payment models, including high prices for many new therapies.

Unmet medical need remains, forcing policy makers to grapple with practical ways to encourage innovation while ensuring that new technologies maximize value and outcomes. Duke-Margolis is formulating policy approaches to spur investment in areas of unmet need, reduce the time and cost of medical product development, and support high-value evidence-based use of drugs, devices, and other technologies. Selected projects are summarized below.

## Exploring Practical Implementation of Incentives for New Antibiotic Development

Dangerous bacteria become resistant to antibiotics faster than new drugs can hit the market. Challenges include scientific difficulties keeping up with fast-evolving bacteria, lack of antibiotics where they are needed, and continuing overuse in health care and agriculture globally. The Centers for Disease Control and Prevention estimates that two million antibiotic resistant infections in the U.S. cause 23,000 deaths at a direct cost of \$20 billion annually.



*Methicillin-Resistant Staphylococcus aureus (MRSA) Bacteria by NIAID (2011)*

Some experts estimate the average cost of developing one new therapy for approval at up to \$2 billion and the process often lasts longer than a decade. A drug manufacturer's return on investment is based on sales volume; however, new antibiotics must be used sparingly and judiciously in order to preserve their effectiveness and slow the time it takes for bacteria to evolve into resistant strains. Combined, these factors create a disincentive to invest in antibiotic development.

Duke-Margolis' Greg Daniel and Gabriela Lavezzari lead a team, including David Ridley from the Fuqua School's Health Sector Management program, that is working toward practical solutions for tackling this problem in the U.S. In 2016, the Center formed an Advisory Group of experts, including pharmaceutical developers, public and private payers, a patient advocate, a physician/science advocate, regulatory organizations, international organizations, and economists. An expert workshop in July gained consensus on the core principles for economic incentives and the feasibility of potential solutions.

In November, a well-attended public meeting gathered stakeholder and community input on three options for sustainable economic incentives to promote innovation, access, drug stewardship, and payment based on value. Final recommendations will be presented in a white paper that will be broadly disseminated. The Center's work has received national and international recognition, with Dr. Lavezzari giving an invited presentation at the World Anti-Microbial Resistance Congress in September and Dr. Daniel providing the keynote at the DRIVE-AB meeting in Oslo, Norway in October. Dr. Daniel also presented invited remarks at a closed-door meeting of the Presidential Advisory Council on Combatting Antibiotic-Resistant Bacteria and a Senate briefing in September.



## Using Real-World Evidence to Inform Clinical and Regulatory Decisions

A growing digital health infrastructure is generating unprecedented volumes of real-world data on clinical practice and patient outcomes. These data, and the evidence derived from them, can inform patient and provider decisions, quality improvement initiatives, and coverage and reimbursement policies to deliver the right treatment to the right patient at the right time.

There have been limited opportunities for medical product developers and the FDA to use real-world evidence in regulatory decision-making.

Challenges with data curation and standardization in electronic health records and other sources of real-world data, with research methods for turning such data into actionable insights, and with underlying incentives and infrastructure for robust data development have hindered progress. Under a collaborative agreement with FDA, Duke-Margolis is laying the foundation for enhanced regulatory use of real-world evidence through a number of public meetings, research activities, pilot opportunities, and white papers – all of which will contribute to emerging policy.



Working with a small planning group of national experts, the Center held several meetings in 2016. A January workshop and March public meeting provided opportunities to gather broad stakeholder input on the methods, data standards, and study designs that could enable more efficient use of this information as part of the FDA's regulatory framework.

In December, the working group met to review in-progress white papers synthesizing this input and to outline additional research and convening activities for 2017. Forthcoming work will establish a high-level vision for where and how real-world evidence could best support a range of regulatory decisions, as well as a more detailed look at readiness for using data from electronic health records. This work will build on the expertise gained by Duke-Margolis staff in helping FDA continuously improve the use of real-world data in the Sentinel System and National Evaluation System for health Technology (NEST).

## Convening Stakeholders to Inform Policy

Duke-Margolis honors the tradition of academic independence on the part of its faculty and scholars. This approach means that Duke-Margolis can serve as an independent and impartial facilitator for broad stakeholder input on significant policy issues.

In 2016, Duke-Margolis convened 16 working group sessions or expert workshops and six public meetings, engaging more than 840 individuals and organizations representing regulatory agencies, providers, patient advocacy organizations, industry, professional associations, payers, legal, policy, academic, and media stakeholders. In addition to the use of real-world evidence to inform regulatory decision making, the Center convened experts to inform policy solutions for communicating about off-label drug use, encouraging drug development for specific infections, using biosimilars, and creating risk evaluation and mitigation strategies — to name just a few. Additional convening work focused on healthcare delivery solutions including new models for cardiac care, the business case for digital health, and developing performance outcome assessments.

The Center's convening work informed the creation of FDA's National Evaluation System for health Technology (NEST), including facilitating the Planning Board, which outlined the need for a Coordinating Center to implement the proposed system in its April 2016 report. FDA then called for proposals for the Coordinating Center, and funded the new center in September 2016. This effort garnered broad support, with industry agreeing to provide additional funding through user fees starting next year. The Center's convening work has also informed other key regulatory policies including innovative approaches to adaptive trial design, promoting development of new therapies for rare diseases, and integrating the patient experience into regulatory decisions.

With major changes in both health care and biomedical innovation, the skills required to succeed and thrive as a health care provider, industry leader, or policymaker must change as well. In a complex regulated environment where multiple individuals and organizations are responsible for delivering quality care, new skills and collaborations must be established to drive needed policy changes. In addition to the initiatives below, the Center will be setting strategy and piloting content for executive and corporate education in health policy.

## Margolis Scholars in Health Policy & Management

Beginning in Fall 2016, Duke-Margolis and the Sanford School of Public Policy partnered to create the Margolis Scholars in Health Policy and Management, with applicants entering the MPP degree program at Sanford in Fall 2017.

This pilot program is a first step in partnering across Duke University to prepare graduate and professional students from a wide variety of backgrounds and programs for cross-disciplinary careers in health policy and management. Corinna Sorenson, PhD, has been appointed faculty director of the Margolis Scholars program, where she will collaborate with leadership across campus to develop new courses in health policy and management, coordinate a seminar series addressing current and emerging health care issues, and design hands-on learning opportunities for graduate and professional students interested in health policy.

Margolis Scholars chosen for Fall 2017 will be linked with Duke-Margolis faculty and staff at Duke and in Washington, DC. Scholars will be considered for



competitive scholarships and paid summer internships that provide hands-on experience in health policy and management. The Margolis Scholars will receive a rigorous academic foundation in the tools of policy analysis combined with health policy and management course offerings in at Sanford and other Duke schools. Classroom experiences will be supplemented with seminars and access to the health policy, sciences, and management expertise across Duke University and Duke Health.

Margolis Scholars will have opportunities to participate in consulting projects, professional skills training, and interaction with policymakers and healthcare thought leaders. In particular, the Scholars will participate in summer internships with leading health care organizations in NC, DC, and elsewhere to apply their coursework and expand their skills and professional networks in health policy and management. Future educational and training initiatives at Duke will build on what is learned through this initial collaboration between Duke-Margolis and the Sanford School's MPP Program.

## Bass Connections Medicaid Reform Advisory Team

Bass Connections is a university-wide initiative launched by a \$50 million gift to Duke University from Ann and Robert Bass. A distinctive model for education, the program provides both graduate and undergraduate students with greater exposure to inquiry across the disciplines, partnership with unlikely fellow thinkers, sustained mentorship in teams and the chance to experience the intersections of the academy and the broader world.

In 2016, Duke-Margolis proposed and was awarded a Bass Connections course. The Bass Connections Medicaid Reform Advisory Team will combine Duke's expertise in public policy, law, medicine, and business to craft a Medicaid reform proposal designed to fit the constraints and demands of North Carolina politics.

After a preparatory "boot camp" in December, team members will investigate the political and legal procedures involved in Medicaid reform as well as potential health coverage models and business opportunities to meet the needs of North Carolina's Medicaid beneficiaries. The team will partner with representatives from advocacy organizations, the Duke Office of Government Relations, health care providers, and community health institutions to ensure that the concerns of a broad range of stakeholders are addressed in the policy proposal. Likewise, team members will meet with state legislators, including chairs of the relevant committees (and/or their staff), to determine the political constraints to any proposed reforms.

Ten undergraduate students and five graduate students from diverse majors and programs join faculty, fellows and staff from Duke-Margolis, the Duke Clinical Research Institute, Duke Schools of Law and Nursing, and community organizations to gather information and propose a solution for North Carolina's Medicaid program under a time frame similar to that required for effective state-level policymaking. The team is led by Barak Richman and Don Taylor.



## Introduction to Healthcare Markets & Policy

Recognizing that practitioners are ideally positioned to make meaningful change to improve the health of individuals and populations, students in the Duke University School of Medicine reached out to Duke-Margolis to create a fourth-year elective course, "Introduction to Healthcare Markets and Policy." Duke-Margolis faculty and affiliates provided background reading, presented lectures, and facilitated discussion on the following topics:

### **Fall 2016**

#### **Introduction to Health Policy and the Role of Policy**

Mark McClellan, MD, PhD

#### **How Do We Pay for Health Care?**

Don Taylor, PhD, MPP

#### **How Do We Regulate Quality?**

Barak Richman, JD, PhD

#### **Healthcare Consumerism**

Peter Ubel, MD

### **Spring 2017**

#### **Pharmaceutical Policy**

David Ridley, PhD

#### **Innovation in Health Care**

Kevin Schulman, MD, MBA

#### **Technology Assessment and Cost Effectiveness Analysis**

Gillian Schmidler, PhD

#### **The Globalization of Health Care**

Krishna Udayakumar, MD, MBA

#### **Population Health**

Lesley Curtis, PhD





Health care is not immune to the challenges and opportunities presented by globalization, and Duke University's global presence allows Duke-Margolis to conduct research and form partnerships for policy impact far outside the borders of the United States. Worldwide, countries are working on ways to improve outcomes and lower costs, including through payment reforms. Accountable care payment reforms focus on aligning payments more closely with what matters most to patients and seek to enable more flexibility and innovation in how and where care is delivered.

## Advancing Payment and Delivery Reform Worldwide

A team that includes Mark McClellan, Krishna Udayakumar and Andrea Thoumi collaborates with partners across the globe to help policymakers adopt accountable care to support transformative steps and innovations in their own countries. Dr. McClellan chairs the Accountable Care Forum for the World Innovation Summit for Health (WISH), a bi-annual health policy summit held in Doha, Qatar and global community of health policy research.

An advisory group comprised of international health policy, payment, and provider leaders works with the research team to expand the 'accountable care framework' to recognize organizational and policy context factors that matter

to implementation of value-based approaches. The team has systematically applied this framework to case studies from diverse economic, geographic, and health policy settings to illustrate how accountable care's explicit focus on achieving better outcomes for a population – backed by a commitment to measure and support progress – can enable patient-centered innovations in care. In 2016, the framework used was showcased at a Health Affairs briefing in Washington, D.C. and the final report was presented at WISH 2016 on November 29-30, 2016 in Doha, Qatar.

## Learning from Global Experiences with Payment Reform

Based on prior work supported by the Commonwealth Fund, the Duke-Margolis team is identifying practical lessons from global experiences with accountable care





that can be adopted by a wide range of policymakers and payers in the U.S. to accelerate health care reform domestically and promote the exchange of best practices and knowledge. An advisory board comprised of health policy, payment, and provider leaders in the U.S. has worked with the team to expand the accountable care framework to include internal (organizational capabilities) and external (policy context) factors that matter as policymakers begin to implement reforms that move toward value-based approaches. The framework has been used to develop in-depth case studies from diverse economic, geographic, and health policy settings – these case studies will be presented at a public event in early 2017.

## Mapping Global Health Research and Development

A team from the Duke Global Health Institute and Duke-Margolis has been contracted by Global Health Technologies Coalition to conduct a formal exploration regarding how the U.S. government could improve its support for global health research and product development, going beyond the funding question to identify who makes decisions about investment in global health research and development. To the best of our knowledge, there has been no formal exploration of stakeholder perspectives on what is working, what is not working, how feasible the policy options are, how recommended solutions would be implemented, or their thoughts on innovative technology.

The final report will identify where decisions get made, when they happen in the legislative calendar, what the “levers” might be for those who wish to advocate for increased funding, and will assess the appetite for change and will include a policy map to inform a more educated advocacy approach with the goal of a more unified R&D strategy and for maximizing the U.S. government investment in pursuit of better health outcomes for low- and middle-income countries. This work is led by Mark McClellan, DGHI founding director Michael Merson, Gavin Yamey (DGHI and Duke-Margolis), and includes David Ridley (Duke-Margolis), Cynthia Binanay (Hubert-Yeargan Center for Global Health), Andrea Thoumi, and Jonathan Gonzalez-Smith (Duke-Margolis).

## Policy Impact: CMS Quality Payment Program

In April 2016, the Centers for Medicare and Medicaid Services (CMS) issued a 952 page proposed rule to establish key parameters for the new Quality Payment Program, including Merit-based Incentive Payment System (MIPS) and Alternative Payment Models (APMs), giving about 60 days for public comment.

A group of Duke-Margolis faculty and staff filed an extensive comment, key aspects of which are reflected in the final rule. Among Duke-Margolis’ recommendations::

- CMS should “create better opportunities for relatively small or specialized practices to participate in Alternative Payment Models (APMs) and Advanced Alternative Payment Models (AAPMs)”. In the final rule, CMS moved to retrofit existing models to allow more small provider practices to participate and will add ACO Track 1+ in 2018, which has lower levels of risk than other ACOs.
- CMS should implement MIPS “in a manner that limits the administrative burden on smaller practices,” and in the final rule, CMS raised the threshold for exemption from MIPS, reducing the number of small practices that will be required to participate. The final rule also allows small providers to form groups for submitting data requirements and different evaluation criteria for small providers who participate in a MIPS APM.
- CMS should provide “better and more timely data” than once a year to help clinicians improve care within the time frame for which they are being evaluated. After 2017, CMS will provide feedback on a more frequent basis.

While Duke-Margolis cannot take sole credit for these changes, the final rule’s emphasis on ways to give more providers access to advanced alternative payment models is an example of the type of policy impact Duke-Margolis can have.



**Mark B. McClellan**  
*Director and Robert J. Margolis, MD, Professor of Business, Medicine and Health Policy*

Mark B. McClellan, MD, PhD, is a doctor and an economist whose work has addressed a wide range of strategies

and policy reforms to improve health care, including payment reforms to promote better outcomes and lower costs, methods for development and use of real-world evidence, and approaches for more effective drug and device innovation. Dr. McClellan is a former administrator of the Centers for Medicare & Medicaid Services (CMS) and former commissioner of the U.S. Food and Drug Administration (FDA), where he developed and implemented major reforms in health policy.

Dr. McClellan has served as a member of the President's Council of Economic Advisors and as Deputy Assistant Secretary of the Treasury for Economic Policy. He was also a Senior Fellow at the Brookings Institution and a professor of economics and medicine at Stanford University where he directed the Program on Health Outcomes Research.



**Gregory W. Daniel**  
*Deputy Director and Clinical Professor, Fuqua School of Business*

Gregory W. Daniel, PhD, MPH, RPh, directs the Duke-Margolis office in Washington, DC. He leads

the Center's pharmaceutical and medical device policy portfolio, which includes policy and data strategies for improving development of and access to innovative pharmaceutical and medical device technologies. His expertise spans post-market evidence development to support increased value, improving

regulatory science and drug development tools, optimizing biomedical innovation, and supporting drug and device payment reform.

Dr. Daniel is also a Senior Advisor to the Reagan-Udall Foundation for the FDA and Adjunct Associate Professor in the Division of Pharmaceutical Outcomes and Policy at the UNC Eshelman School of Pharmacy. Previously, he was Managing Director for Evidence Development & Biomedical Innovation in the Center for Health Policy and Fellow in Economic Studies at the Brookings Institution and Vice President, Government and Academic Research at HealthCore (subsidiary of Anthem, Inc.). Dr. Daniel's research expertise includes utilizing electronic health data in designing research in health outcomes and pharmacoepidemiology, comparative effectiveness, and drug safety and pharmacoepidemiology.



**Victoria Christian**  
*Chief Operating Officer*

Victoria Christian has held executive leadership roles in clinical and translational research for pharmaceutical, biotechnology, CRO, and academic organizations.

Before joining Duke-Margolis, she was COO of the Duke Translational Research Institute (DTRI), a central institutional resource for translational researchers. Ms. Christian played an instrumental leadership role in the conceptualization, design, and launch of the Measurement to Understand Re-Classification of Disease of Cabarrus County and Kannapolis (MURDOCK) Study, a major molecular epidemiology initiative made possible by a gift from David H. Murdock. She has held multiple positions at Duke University, where her operational leadership was crucial to the success of large clinical trials.

She has held senior level positions at PAREXEL International and King Pharmaceuticals, and founded NITROX LLC, a Duke spin-out company in 2004.

Ms. Christian has served as Vice President of Duke Medical Strategies, Inc., as Co-Chair for the Duke Medicine Enterprise-Wide Academics Planning Committee, and as Steering or Board member for the Duke Biobank, the Coulter Program, the Stem Cell Research Oversight Committee, and the Biomarker Factory. In January 2016, Victoria was recruited to serve on The Clinical Center Working Group of the NIH Director's Advisory Board.



**Ellen de Graffenreid**  
*Director of Communications*

Ellen de Graffenreid, MA, MBA, previously served as vice chancellor for marketing and communications at the University of Missouri and

senior vice president for communications at Brandeis University, overseeing branding and marketing, media relations, university publications, digital communications, official social media channels, trademarks and licensing, and creative services.

She has spent the majority of her career in higher education and academic medicine, serving as director of communications and marketing at the University of North Carolina Lineberger Comprehensive Cancer Center and UNC Cancer Care, the University of Louisville Health Sciences Center, and as vice president of communications and donor relations at the Washington State University Foundation. She has garnered multiple awards from the Council for Advancement and Support of Education and the American Association of Medical Colleges' Group on Institutional Advancement.



**Lesley Curtis, PhD**  
 Professor of Medicine,  
 General Internal Medicine  
 Director, Center for Pragmatic  
 Health Services Research in the  
 Duke Clinical Research Institute



**Eric Peterson, MD, MPH, FA**  
 Fred Cobb Distinguished Professor of  
 Medicine in the Division of  
 Cardiology, DukeMed Scholar, and  
 Executive Director of the Duke  
 Clinical Research Institute (DCRI)



**Don Taylor, PhD, MPP**  
 Professor in the Sanford School  
 of Public Policy  
 Assistant Professor of Community  
 and Family Medicine  
 Associate Professor in the  
 School of Nursing  
 Affiliate, Duke Global Health  
 Institute  
 Affiliate of the Duke Initiative  
 for Science & Society  
 Member of the Duke Clinical  
 Research Institute  
 Member of the Duke Cancer  
 Institute



**Krishna Udayakumar, MD, MBA**  
 Associate Professor of the  
 Practice of Global Health,  
 Duke Global Health Institute  
 Associate Professor - Track IV  
 in Medicine, General Internal  
 Medicine



**Adrian Hernandez, MD, MHS**  
 Professor of Medicine, Cardiology  
 Associate Director,  
 Duke Clinical Research Institute



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 Edgar P. and Elizabeth C. Bartlett  
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 School of Business  
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 Public Policy  
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 Internal Medicine  
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 Affiliate of the Duke Initiative for  
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 Duke University Health System  
 Associate Professor of Medicine  
 and Pediatrics



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 of Business and Economics  
 Faculty Director of the Health  
 Sector Management program,  
 Fuqua School of Business

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Medical & Program Director, Care Redesign Program; Assistant Professor of Medicine, Hospitalist Physician

**Jeff Clough, MD, MBA**

Assistant Professor of Medicine, General Internal Medicine

**Zubin Eapen, MD**

Associate Professor of Medicine, Cardiology Director, Duke Heart Failure Same-Day Access Clinic  
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**Bradi Granger, PhD**

Associate Professor of Nursing, Associate Director of Duke Translational Nursing Institute, Director of the Duke Heart Center Nursing Research Program

**Adrian Hernandez, MD, MHS**

Professor of Medicine, Cardiology  
Associate Director, Duke Clinical Research Institute

**Erich Huang, MD, PhD**

Assistant Professor in Biostatistics and Bioinformatics, Assistant Professor of Surgery

**Nandan Lad, MD, PhD**

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Member, Duke Cancer Institute

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**Gillian Sanders Schmidler, PhD**

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Professor of Biostatistics and Bioinformatics  
Member, Duke Clinical Research Institute

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Professor in the School of Nursing  
Professor of Public Policy Studies, Sanford School of Public Policy

**Gavin Yamey, MD, MPH**

Professor of the Practice of Global Health, Duke Global Health Institute  
Professor of the Practice in the Sanford School of Public Policy

**Yousuf Zafar, MD**

Associate Professor of Medicine, Medical Oncology  
Assistant Professor in the Sanford School of Public Policy  
Member of the Duke Cancer Institute  
Affiliate, Duke Global Health Institute  
Member in the Duke Clinical Research Institute



## Research Directors

**Heather Colvin, MPP**  
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**Matthew Harker, MBA, MPH**  
Project Director – Evaluation Hub

**Gabriela Lavezzari, PhD, MBA**  
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## Senior Policy Advisor

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Associate Professor of Medicine & Public Health  
Associate Director of the Office of Clinical Practice Innovation  
George Washington University

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**Zeena Johar, PhD**

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Research Associate

**Mary Barks**  
Duke-Ipsos Center Lab Manager

**Will Bleser, PhD**  
Research Associate

**Jonathan Bryan**  
Research Assistant

**Jessica Burnell**  
Research Assistant

**Sarina Coates**  
Research Assistant

**Kelly Davis**  
Research Associate

**Katherine Frank**  
Senior Research Assistant

**Meredith Freed, MPP**  
Senior Research Assistant

**Jonathan Gonzalez-Smith, MPA**  
Senior Research Assistant

**Katie Greene, MPP**  
Research Associate

**Matthew Harker, MBA, MPH**  
Associate Director, Health Policy Evidence Hub  
Duke Clinical Research Institute

**Madeline Katz**  
Research Assistant,  
BECR Center

**Christine Kirby, MA**  
Research Associate

**Mark Japinga, MPA**  
Senior Research Assistant

**Andrew Olson, MPP**  
Project Leader, Health Policy Evidence Hub  
Duke Clinical Research Institute

**Jingyuan “Juan” Qian, MPP**  
Senior Research Assistant

**Elizabeth Richardson, MSc**  
Managing Associate

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Research Associate

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Research Associate

**Andrea Thoumi, MSc, MPP**  
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## Haongmai Pham joins Duke-Margolis as a Senior Research Fellow

In January 2017, Haongmai (Mai) Pham, MD, MPH, joined Duke-Margolis as a Senior Research Fellow. She is a general internist and was formerly Chief Innovation Officer at the Center for Medicare and Medicaid Innovation (CMMI), where she was responsible for implementation of the alternative payment model provisions of the Medicare and CHIP Reauthorization Act, and other cross-cutting initiatives for the Center. Dr. Pham was previously Director of the Seamless Care Models Group in CMMI, where she oversaw the design and testing of models on accountable care organizations and advanced primary care, including the Pioneer and Next Generation ACO Models, Comprehensive Primary Care Initiative, and Comprehensive ESRD Care Initiative. Before coming to CMS, Dr. Pham was Senior Health Researcher and Co-Director of Research at the Center for Studying Health System Change and Mathematica. She has published extensively on care fragmentation and coordination, quality reporting and improvement, health disparities, and provider market trends, and the intersection of each of these with payment policy. Dr. Pham provided primary care at safety net organizations for many years.



The Duke-Margolis model has been enthusiastically endorsed by stakeholders ranging from policymakers and policy implementers, to industry, payers and providers, to patients and advocates who share the desire to improve healthcare quality, lower costs, encourage innovation, and enhance patient safety.

The Center is grateful to the members of our world-class advisory board, who have agreed to give their time and expertise to guide and refine our strategy and connect us with experts across the spectrum of research, policy, practice, and patient care.

**Robert Margolis, MD**  
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Duke University Health System



## Financial Overview

In the first twelve months of operations Duke-Margolis successfully transferred ongoing grants and a productive health policy research group from the Brookings Institution and established offices in Washington, DC and on the Duke University campus. Transferred grants and additional awards made during the calendar year totaled \$11,290,000. Key personnel including a Chief Operating Officer, Director of Communications, and Research Directors were recruited to the Center to manage and develop the programming.

Approximately half of the first year's expenses (\$1,313,752) covered professional, research, and support staff. The remainder was used to create infrastructure, equip office space, and supplement brisk convening activity with modest funding for expenses that cannot be covered by federal grants. Substantial funding has been set aside in fiscal year 2016 to offset the expense of expansion and moving for both the Washington and Durham operations in fiscal year 2017. Duke University's fiscal year runs from July 1 to June 30.

Duke-Margolis faculty and staff  
have published research in multiple  
peer-reviewed journals.

Please visit

[https://healthpolicy.duke.edu/  
2016 Publications](https://healthpolicy.duke.edu/2016-Publications)

to learn more.

## Research Funders and Sponsors

Duke-Margolis is grateful to the organizations that have provided unrestricted funds and sponsored research agreements to further its mission of improving health and the value of health care by developing and implementing evidence-based policy solutions locally, nationally, and globally.

Aetna Foundation, the American Public Health Association and the National Association of Counties

American College of Cardiology Foundation

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