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50 YEARS OF THE "HOW" IN HEALTH CARE

By Christina Hernandez Sherwood

Established in 1967 to address the complexities of Medicare and Medicaid, the Leonard Davis Institute of Health Economics has had a lasting impact on national policy and on the strength and nature of interdisciplinary health inquiry at Penn.

They came from Penn Medicine and beyond—oncologists, economists, health care policy analysts, medical ethicists, lawyers, regulators, insurance and pharmaceutical executives and patient advocates—for a first-of-its-kind meeting to tackle a question that touches them all: What is the economic sustainability of precision cancer medicine?

Patients with cancer face not only the disease itself, but also the difficult choice of treatments from among the array on the market. These include precision cancer medicine, which uses a patient's own characteristics to fight cancer in an individualized approach. "[It] holds promise not just to cure their cancer, but to do so with the appeal of exactness," said Justin Bekelman, MD, an associate professor of Radiation Oncology, and Medical Ethics and Health Policy, at the Perelman School of Medicine. "That is so highly alluring that they're almost too good to give up." Yet as it stands now, he said, precision cancer therapies are expensive. And despite some high-profile successes, such as the personalized immune cellular therapy developed at Penn and recently approved by the FDA (see p. 3), precision therapies as an approach haven't proved more effective on average than traditional treatments.

Bekelman and Steven Joffe, MD, MPH, chief of the Division of Medical Ethics, lead the Gant Family Precision Cancer Medicine Consortium, established last year to help cancer patients, their providers, and insurers make informed care decisions by providing greater transparency on the price and effectiveness of precision cancer medicine. "[We] felt very strongly that bringing together people of diverse backgrounds, diverse scholarship, diverse experiences would lend a 'special sauce' that would help us drive toward sustainable solutions to the problem," Bekelman said.

While the topic the consortium addresses is decidedly modern, a collaboration of this nature, with stakeholders from academia, industry, and government convening to talk about costs, is an occurrence with a long history. That it happened at Penn is no accident. This conversation can trace its origins back a half century.

THE BEGINNING

President Lyndon B. Johnson signs into law the bill that will establish Medicare and Medicaid.

It was the mid-1960s when the health insurance magnate Leonard Davis picked up the phone and dialed the Wharton school. Davis and his wife, Sophie, had founded the Philadelphia-based Colonial Penn Group in 1963 to sell health insurance to people over 65. When he reached Wharton's dean, Davis said he was prepared to make a six-figure gift to the school to establish an institute focused on health economics. And then, as the story goes, the dean replied, "What's that?"

It wasn't an unreasonable question. As the infrastructure of Medicare and Medicaid was being built from the ground up, Americans were only beginning to address the complex questions of what this new health care structure should look like, and how it would balance accessibility, affordability and quality. Then a fringe interest within insurance, the field of health economics had only begun to stand on its own.

Despite the initial confusion, in 1967 the Leonard Davis Institute of Health Economics (LDI) opened its doors. As a link between University of Pennsylvania schools, convening faculty from medical, business, nursing, law, and other schools without sitting under any one of them, LDI was perfectly poised to address the interdisciplinary questions of health economics by sharing the expertise of leaders in these diverse areas. "The fact that economics and health care are so critically intertwined, I don't think was as generally appreciated at that time as Leonard Davis recognized it to be," said David Asch, MD, MBA'89, GME'87, who was LDI's executive director from 1998 to 2012 and now runs the Penn Medicine Center for Health Care Innovation. "This was prescient and important. It makes LDI one of the first programs in the country to recognize that."

Over the decades, this interdisciplinary inquiry into emerging questions germinated seeds that have bloomed across Penn's campus. LDI was instrumental in the creation of many research groups, departments, and centers that now populate Penn's health economics universe, such as Wharton's Health Care Management Department in 1968, the Division of General Internal Medicine in 1978, the Center for Health Incentives and Behavioral Economics in 2008, and the Department of Medical Ethics and Health Policy at the Perelman School in 2011, and more. "These groups now sit as satellites and operate independently from LDI but were developed with the LDI DNA embedded into them and remain interconnected through LDI," said Dan Polsky, PhD, MPP, who has been the institute's executive director since 2012.

"My work has been done with people in every other one of the ten schools of the university, other than Medicine and the Wharton School, where my appointments are," said J. Sanford Schwartz, MD'74, LDI's executive director from 1989-98, during a 50-year alumni panel this spring. "I think LDI has played a fundamental role in intellectual and academic enrichment of the whole campus."

By the time the Gant consortium held its capstone in-person meeting this past May, ready to take on the economics of precision cancer medicine, the stage had been set. Both Bekelman and Joffe are LDI senior fellows and, though not directly under the institute's umbrella, the consortium also has LDI's DNA embedded. It adheres to the institute's philosophy of seeking solutions to the problems of health economics by collaborating across boundaries. Consortium members debated questions including: What drives the cost of precision cancer drugs? Are all precision cancer drugs a home run, or are some base hits, if that? How does the United States handle precision cancer medicine in comparison to other countries? And, is cancer special?

Leonard and Sophie Davis

"The topic area seems to me a perfect fit for the kind of work that LDI's mission sets out to do," Joffe said. "Without something like LDI at Penn, we wouldn't have had the depth and breadth of talent here to be able to do this at the same level."

IMPORTANT QUESTIONS ON THE NATIONAL STAGE

President Richard Nixon signs into law the bill encouraging the creation of HMOs.

Early on, LDI's work stretched outside Penn as well—all the way to Washington. During his time as a special assistant to President Richard Nixon, Robert Eilers, MBA, PhD, the institute's founding director and a Wharton insurance professor, helped develop national health insurance policies and health maintenance organizations. Eilers' work provided much of the basis for 1973's Health Maintenance Organization Act, which encouraged the creation of HMOs.

About a decade later, LDI had garnered enough clout to attract leading health services researchers and policymakers from across the country to a 1981 meeting. Attendees formed the Association for Health Services Research, which is now known as AcademyHealth, the world's leading professional society devoted to health policy.

By 1984, Leonard Davis had sold Colonial Penn and made philanthropy his full-time endeavor. He'd moved on to other causes, but continued to support LDI with annual gifts, and remained interested in its work. Near his New York City foundation office, Davis met for yearly lunches with Mark Pauly, PhD, the Wharton health care management and business economics professor who was the institute's executive director from 1984 to 1989. "We would talk a lot about [whether] people have the right to health care," Pauly said. "[Davis] thought they did and was, in a way, trying to do his small part to improve that when he was selling health insurance to the elderly. He had some money to devote philanthropically, which he was willing to do, but he wasn't just going to just throw it away. He wanted to pay attention to results."

Back at LDI, the end of Pauly's tenure was highlighted by a grant to serve as a Medicare Research Center, which entailed taking on Medicare assignments. Pauly convened a group of thinkers to tackle one such task: brainstorming alternative methods of physician payment. The final product, a book about the pros and cons of issues including capitation and salary, was released in 1991, but the physician payment question remains timely today, as does Pauly's earlier work on the individual mandate. "You do the research mostly because you find it interesting and you think it addresses potentially important problems," he said. "You set out the answers, and you wait for the questions."

Photo by Hoag Levins

Justin Bekelman, MD, speaks to members of the Gant Family Precision Cancer Medicine Consortium, which he co-leads with Steven Joffe, MD, MPH.

Illustration by ImageThink

Conversations at the Gant consortium's in-person meeting spanned clinician, patient, drug industry, insurance industry, regulatory, and other perspectives.

For its part, the Gant consortium has settled on one particular answer that is crucial to modern economic questions about precision cancer medicine: Cancer is special—at least, the world treats it that way. The unanswered questions that surround this answer are more complex: Why is the health care system willing to pay higher prices for cancer drugs than comparable medications? Is it ethical to treat cancer as special? "The [cancer] diagnosis is treated differently than other diagnoses," Bekelman said. "That informs how we think about the potential solutions to address the high pricing of these drugs."

ORGANIZING ACADEMIA, REACHING BEYOND

President Bill Clinton delivers his proposal for universal health insurance.

When Asch took LDI's helm in 1998, one of his first projects was to examine the policy questions related to testing women for the BRCA gene mutations that had been found to increase the risk of breast cancer. While life insurers wanted access to patients' BRCA results, consumer advocates worried this would lead to discrimination. Using actuarial modeling, the team determined that shielding BRCA results from insurers would not create a so-called "death spiral" that could threaten the companies' financial solvency.

It was the ideal interdisciplinary problem for both Asch, an internist focused on how health-related decisions are made, and for LDI itself. "We had a principle we followed when I was the director, which was that LDI would do the kinds of things that were hard for individuals, but easier for groups," he said. "One of the things LDI has always done is organize the academic community."

The institute was also expanding its education efforts, which started in 1973 with Penn's selection as an early site of the Robert Wood Johnson Foundation Clinical Scholars program. In 1999, LDI established its Summer Undergraduate Minority Research program to give college students the opportunity to work with research faculty. The project was dreamed up by Pauly, then deputy dean for Wharton's doctoral programs, and LDI's Deputy Director Joanne Levy, to create the minority candidates that universities were fighting over.

It was one of the last major LDI projects the Davises lived to see. Sophie and Leonard Davis died, within four months of each other, in 2000 and 2001 respectively. At the time of their deaths, the couple granted one last gift to the institute, a donation that brought their total support of LDI to more than $4 million.

The 1990s also brought change in LDI's approach to engaging with policy. In the years following President Clinton's controversial proposal for universal coverage, the national health care debate veered from policy into politics, and it became increasingly difficult to turn research into change. To reach a broader spectrum of stakeholders, including politicians and their staffs, and take advantage of the burgeoning internet, LDI began to disseminate its work in non-traditional ways. While LDI faculty focused on research, the institute hired a communications guru to relay its message. "You want to be academic and scholarly and rigorous," Asch said, "but you also want to be relevant and readable and actionable."

Soon LDI was publishing digital issue briefs that were indexed on MEDLINE and accessible to reporters. The institute launched its own magazine and digital media channels. "We ended up with our own, really one of the first, media presence aimed at communicating scholarship," Asch said, "not in a dumbed down way, but in a way that was understandable for relevant stakeholders."

The approach endures. Over the last year, to keep stakeholders and the public in the loop, LDI's blog has featured updates on the major topics discussed remotely by the Gant consortium in the run-up to its first in-person meeting in May. In the coming months, the consortium expects to publish its recommendations for policies around precision cancer medicine. "There's so much discussion and debate

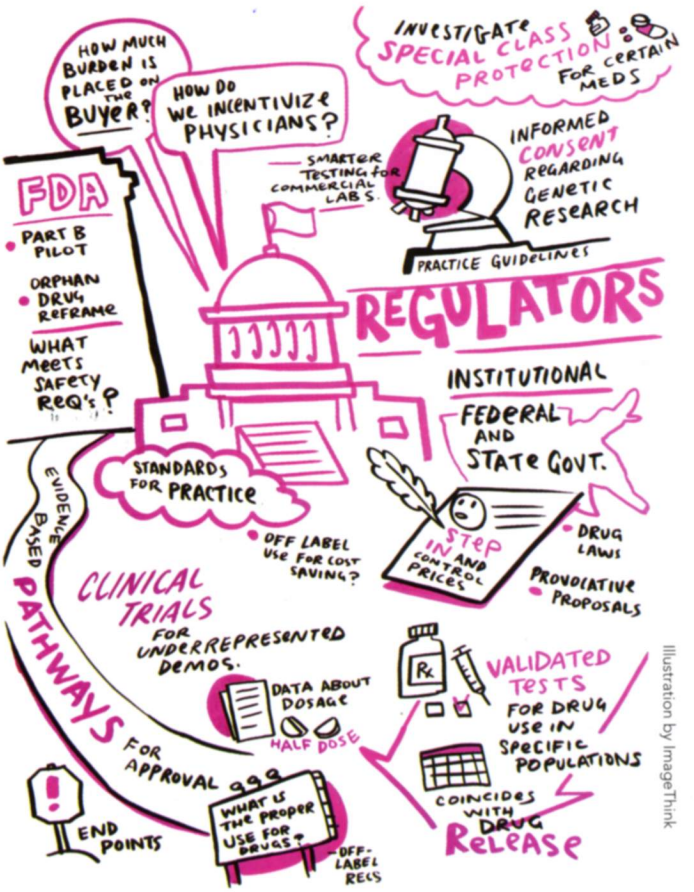

Illustration by ImageThink

about approaches to dealing with drug prices right now," Joffe said. "It gives us an opportunity with a really well thought-out set of ideas to put them in front of people who are looking for good ideas."

WORKING FOR EVIDENCE IN POLICY, VALUE IN CARE

President Barack Obama signs into law the Patient Protection and Affordable Care Act (ACA).

The passage of the ACA was perhaps the biggest health care policy moment since LDI's establishment. "That allowed us to spread our wings and realize we had an awful lot of knowledge we were sitting on," said Janet Weiner, PhD, MPH, LDI's associate director for health policy, who Asch hired in 1999 to communicate the institute's message. "It challenged us to get it out there in ways people could understand and, even further than that, to have an impact."

The institute published a four-part issue brief on various aspects of the ACA, including some of Pauly's decades-old work on the individual mandate. With Polsky as executive director, LDI's major drive was to inform the implementation of health insurance exchanges and individual insurance markets. "We've been very much connected to trying to understand the implementation of the Affordable Care Act," he said.

Alan Davis, who in 2001 took over his parents' foundation with his brother Michael, said LDI is moving in a direction he believes his father would have appreciated. "He was hopeful that through the research and public policy and public exposure a university can generate," Davis said, "[the institute] would move the health care agenda for the United States toward more accessible and affordable care."

When President Donald Trump assumed office this year with his party holding the majority in both chambers of Congress, the new politics and rapid pace of voting on health care legislation precipitated a drastic turn. On the train to Washington early on March 7, Polsky was feverishly reading the House Republicans' ACA replacement bill, which had been released the night before. Arriving at LDI's conference on health reform, which featured panels of market and coverage experts, Polsky was exhilarated, though not entirely comfortable. "We're positioned to present nonpartisan evidence and analysis rather than comment on the daily ups and downs of the political debate," he said.

Now, Polsky said, LDI has again shifted focus, advocating for the use of evidence and knowledge to inform evidence-based policy. "It wasn't something we had to advocate for [previously]," he said.

Today's political tumult makes LDI's work even more relevant, Weiner said. "In some ways, we are heading back to our roots of bringing people together," she said, with "more personal and deep contacts with policymakers who, at this point, are desperate to find non-partisan information they can rely on."

The work of the institute's 250 fellows, who are leading sessions at LDI's 50th anniversary symposium in October, reflects the larger shift of the public health care debate from policy to politics. While LDI's early work was on health care reform issues, such as insurance and finance, Polsky said the current political climate "has pushed more people into areas of health care where they can see impact on their work," he said. "Health care reform has become so politicized that we've seen more of our experts focus their efforts around trying to transform our health care delivery system toward value."

Photo by Hoag Levins

Dan Polsky, PhD, MPP

That emphasis is also evident in the aftermath of the Gant consortium's inaugural meeting. In addition to publishing recommendations, some participants might launch pilot projects to implement the ideas that came up through its discussions. The consortium's goal, like that of LDI, is to both propose solutions and help them find a place in the real world.

As for the institute's future, Polsky sees the potential for LDI to develop innovative solutions to emerging challenges. For example, senior fellows are now working together to tackle a variety of aspects of the opioid crisis and engage policy makers and stakeholders at the local, state, and national level. "LDI in the next 50 years should be known for its contribution to improved health and health care," he said. "The energy our experts are devoting to the opioid crisis offers hope that the epidemic will soon abate; our cross-disciplinary approach allows for new ways of solving difficult problems." ▽

Read this article online with related links, including links to ongoing coverage of the LDI 50th anniversary symposium held in October 2017, at PennMedicine.org/magazine/LDI50

CANCER AND THE COSTS OF SPECIAL TREATMENT

Is cancer "special" in terms of the public view and the value placed on potential treatment and cures? In one of the group's conversations leading up to its first in-person meeting, the multidisciplinary Gant Family Precision Cancer Medicine Consortium discussed whether cancer is treated differently from other diseases. Then it turned to the question of whether it *should* be treated differently.

The first answer is clear. Cancer is special. The many ways include the fear it evokes, the language used to describe it, and the level of research funding devoted to it. Multiple surveys indicate that people fear cancer more than almost any other condition. That fear may underlie the language used to describe initiatives to treat or cure cancer, such as "conquering this dread disease" in Nixon's 1971 "War on Cancer "or the current cancer "Moonshot" aimed at winning that war. Cancer, as described by oncologist Siddhartha Mukherjee, remains "The Emperor of All Maladies."

Both government and industry fund cancer research at levels disproportionately higher than the population disease burden, at least by conventional measures. Cancer accounted for 16 percent of all NIH funding ($5.6 billion) in 2013, and 25 percent of all medicines in clinical trials, according to a report published in the *Journal of the American Medical Association* in 2015.

However, cancer research is not uniformly overfunded relative to disease burden, but instead varies by individual cancer. In terms of National Cancer Institute funding, overfunded cancers include breast cancer, prostate cancer, and leukemia; underfunded cancers include bladder, esophageal, liver, oral, pancreatic, stomach, and uterine cancer. One member of the Gant consortium noted that cancers that carry stigma or can be connected to personal behavior such as smoking, tend to be underfunded.

Cancer is also potentially special in cost of care. Industry has been rewarded for its considerable investment in cancer drugs by prices that are high in absolute terms, as well as by conventional measures of value. By one such measure, the market seems to be willing to pay more for cancer drugs than for other drugs—on average more than twice as much for cancer drugs than for non-cancer drugs in the past decade, according to a recent review.

"Consumers seem to value avoiding a year of life lost to cancer more than a year of life lost to other diseases," one consortium member said. "If they fear some causes of death more than others, so be it."

But *should* we treat cancer differently? The "so be it" attitude toward cancer's exceptionalism is far from a settled consensus. The question of whether cancer *should* be

Photo by Hoag Levins

treated differently is much harder to answer than whether it already is. It raises ethical questions of how to allocate care and funding if some diseases are thought of as more deserving than others.

One group member posited that high prices for cancer drugs are a natural consequence of the free market: The public willingness to pay more for cancer drugs creates a market that bears higher prices. And one challenge, at least in the U.S., is that the third-party payer system obscures the public's view of the true costs of these drugs.

What does this all mean for precision medicine? One consortium member said that the "specialness" of cancer—lying at a scientific frontier of genomics and being well-funded for research—makes it a paradigm of a precision medicine disease. The affected population is large enough to allow for targeting smaller subgroups but small enough to allow for focused attention on a limited number of pathways.

And the potential for breakthrough treatments or cures also lies behind the considerable resources devoted to cancer research, as one consortium member pointed out, because cancer often lies at the cutting edge of science.

Thus, in addressing the economic sustainability of precision cancer medicine, the consortium's work may use the exceptionalism of cancer to understand issues that will arise in precision medicine for other conditions. In this work, paradoxically, the exceptional opens the door to the generalizable and—maybe—opens a window onto the future of precision medicine itself.

– Janet Weiner, PhD, MPH

A version of this article was originally published on the LDI HealthPolicy$ense blog. The blog is one of the ways that the Leonard Davis Institute of Health Economics disseminates its scholarly work to a wide array of stakeholders, including politicians and their staff and industry leaders.