PMC PERSONALIZED MEDICINE COALITION

PERSONALIZED MEDICINE IN BRIEF

VOL. 17, FALL 2021

Developments in Brief

2021

SEPTEMBER 28

In an article that promises to help swell public support for research and public policies designed to advance personalized medicine, *Vice* magazine spotlights the significance of PMC's efforts to break the mold of one-size-fits-all medicine for patients with suspected rare diseases.

PAGE 10

AUGUST 26

A report from the Congressional Budget Office raises questions about the outlook for developing personalized treatments by estimating that 34 fewer drugs would be developed over the next three decades if drug pricing legislation under consideration were enacted.

PAGE 5

AUGUST 10

The Biden Administration rescinds the Most Favored Nation (MFN) model for drug pricing, bolstering the reimbursement outlook for certain personalized treatments. Still, the Administration has signaled an interest in policies the pharmaceutical industry contends would hamper innovation and disrupt access to life-saving medicines.

PAGE 4

JULY 8

A new study in *Nature* reports that more than a dozen parts of the human genome are linked with either enhanced susceptibility to Covid-19 infection or an increased likelihood of severe Covid-19 symptoms. Researchers say the study may anticipate "precision medicine for infectious disease."

PAGE 9

MAY 28

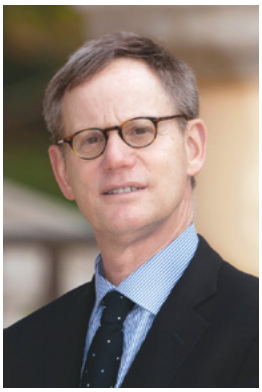
FDA approves Lumakras (sotorasib) for the treatment of non-small cell lung cancer patients with a specific genetic mutation. By inhibiting the function of a cancer-driving protein once considered "undruggable," Lumakras underlines how personalized medicine is expanding the scientific possibilities for treating cancer patients.

PAGE 10

PRESIDENT'S LETTER

Progress Despite the Delta Variant

by Edward Abrahams, PMC President



Dear Colleague:

As was the case for the rest of the world in 2021, the Delta variant created a new obstacle for PMC whose dimensions are still taking shape. Nevertheless, the Coalition has managed to maintain its momentum across multiple fronts. With an enhanced infrastructure for educating policymakers and patients, thriving advocacy programs, and a rapidly maturing research portfolio, PMC is well-positioned to carry its momentum into the *16th Annual Personalized Medicine Conference* in Dana Point, CA, which has been rescheduled for May 19 and 20, 2022.

In this context, I am pleased to introduce the Fall 2021 edition of *Personalized Medicine in Brief*, which documents our progress in education, advocacy, and evidence development. The newsletter anticipates an even stronger 2022 in which we continue to advance a new paradigm in medicine for the benefit of both patients and health systems.

In her "Public Policy Brief" on pages 4 and 5, PMC Senior Vice President for Public Policy Cynthia A. Bens reports on an informational video program showcasing the Congressional Personalized Medicine Caucus that features the four co-chairs. The program presents four Members of Congress from across the political spectrum discussing personalized medicine's potential positive impact on health care, suggesting that our educational work is paying off and will pay dividends in creating more friendly public policies in the future.

As mentioned on page 10, PMC has further bolstered its educational work by launching an enhanced patient engagement platform on www.mtan.org that will serve as a clearinghouse for informative articles about personalized medicine. Augmented by a partnership with Mediaplanet that will bring PMC's messages to more than one million people at a time through its digital channels and printed educational inserts in the *USA Today*, the *More Than a Number* initiative gives PMC an unprecedented capacity for shaping public opinion in the United States.

As explained by PMC Senior Vice President for Science Policy Daryl Pritchard, Ph.D., (see pages 6 and 7), the Coalition has also expanded its science policy programs to include nine studies designed to define and address outstanding challenges facing the field. By shedding light on clinical integration challenges and bolstering the base of evidence demonstrating the clinical and economic utility of personalized medicine, these workstreams promise to inspire continued efforts to facilitate patient access to personalized medicine among both payers and providers.

Finally, on pages 8 and 9, PMC Vice President for Public Affairs Christopher Wells shares a "Perspective on Public Affairs" in which he contends that personalized medicine will become increasingly relevant in the months and years ahead. The article demonstrates the importance of aligning health care policies and practices more closely with the wide-ranging needs and preferences of diverse patient populations.

We continue to believe that patients deserve nothing less.

Sincerely yours,

Edward Abrahams

Edward Abrahams
President

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PUBLIC POLICY BRIEF

Advocates Take Stock of Incrementally Improving Outlook for Personalized Medicine With Cautious Eye on Shifting Reimbursement Headwinds

by Cynthia A. Bens, PMC Senior Vice President, Public Policy

As we approach the final quarter of the Biden Administration's first year in office, personalized medicine's advocates in Washington are taking stock of an incrementally improved outlook for personalized medicine while casting a cautious eye on shifting reimbursement headwinds. Although many policymakers have yet to develop a comprehensive understanding of the opportunities and challenges facing personalized medicine, Congressional lawmakers and officials at the Centers for Medicare and Medicaid Services (CMS) have signaled plans to address some of the regulatory and reimbursement issues inhibiting progress in the field. Their willingness to adopt public policies designed to encourage the advancement of personalized medicine underlines the commonsense appeal of targeting the right medical interventions to the right patients at the right time.

In Congress, the four co-chairs of the Personalized Medicine Caucus have recorded statements about the importance of personalized medicine for publication on PMC's website. Presented as a program titled *Congress and Personalized Medicine: The Perspectives of the Co-Chairs of the Personalized Medicine Caucus*, the videos promise to raise the profile of personalized medicine among lawmakers and their constituents.

In another signal of growing enthusiasm for personalized medicine in Congress, Reps. Diana DeGette (D-CO) and Fred Upton (R-MI) have released a discussion draft of a second *21st Century Cures Act* with multiple provisions that could improve the prospects for the field. These provisions include one that would streamline the regulatory pathway for digital health technologies that may expand the frontiers of personalized medicine by making it easier for researchers to collect and analyze data on a wider range of biological and environmental factors influencing patients' health. The bill also includes language under development by Reps. Eric Swalwell (D-CA) and Scott Peters (D-CA) that would provide for a National Academy of Medicine study and a demonstration project to explore whether expanded Medicaid coverage of some genetic tests and genomic sequencing could enhance care for patients with rare diseases. In a comment letter to Reps. DeGette and Upton, PMC explained how *Cures 2.0* could be further improved to better alleviate "obstacles impeding the integration of personalized medicine that are caused when scientific developments outpace updates to our regulatory, coverage and payment, and health care delivery systems."

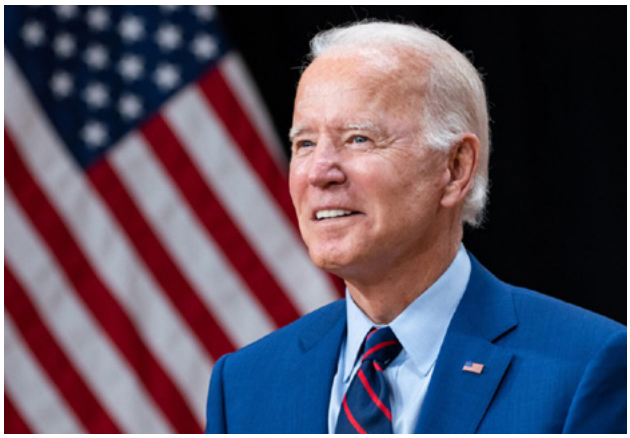
For their part, CMS officials have taken steps to improve the reimbursement prospects for certain personalized treatments. CMS has finalized its plans to maintain boosted payment rates in 2022 for chimeric antigen receptor (CAR) T-cell therapies that re-engineer a patient's own immune cells to combat cancer. The continuation of this policy will help ensure patients have access to a groundbreaking class of personalized treatments. At least for the time being, the agency has also chosen to forego the implementation of the Trump Administration's Most Favored Nation (MFN)

"Congressional lawmakers and federal officials have signaled plans to address some of the regulatory and reimbursement issues inhibiting progress in the field."

policy, which was intended to reduce the cost of prescription drugs in the United States by aligning the prices for the top 50 Medicare Part B drugs with the lowest prices available in economically similar countries. As PMC pointed out in a letter to CMS Acting Administrator Elizabeth Richter in January, the MFN model would have forced some patients to forgo potentially life-saving personalized treatments that other countries do not provide adequate reimbursement for.

But price controls remain a looming threat.

Lawmakers are circulating many bluntly targeted proposals for decreasing drug spending with no discernable mechanism for protecting patient access to personalized treatments designed to decrease downstream costs by addressing the root molecular causes of each patient's disease instead of counteracting daily symptoms. The Congressional Budget Office (CBO) recently analyzed the impact some of these legislative proposals could have on new drug development. In August, the CBO reported that over the next three decades there may be 34 fewer drugs developed if proposals currently under discussion are adopted. In several op-eds published in the *Boston Globe*'s health care affiliate, *STAT*, PMC President Edward Abrahams has argued that such policies could set back personalized medicine by driving a renewed push for the pharmaceutical industry to focus on inexpensive daily maintenance medications rather than personalized medicines whose markets are small but whose value is great. Reimbursement concerns are also evident in the diagnostics arena, where the high cost of evidence generation continues to inhibit the utilization of some genetic testing and genomic sequencing.



Although the outlook for personalized medicine has improved incrementally under the administration of President Joe Biden, advocates in Washington have a cautious eye on drug pricing proposals with uncertain implications for the field.

Advancing personalized medicine in the months and years ahead will require a continued focus on educating policymakers about the need to coordinate public policies across a broader range of fronts to ensure that personalized medicine delivers on its promise of a more effective and efficient health care system. As PMC pointed out in its October letter on CMS' decision to rescind the MFN Model, health care leaders from multiple sectors of the health care system remain confident that this approach "holds the greatest potential for improving patient outcomes and reducing overall health care costs" based on its ability to target treatments to those who will benefit.

SCIENCE POLICY BRIEF

Accelerating Progress in Personalized Medicine by Developing Clinical Utility Evidence

by Daryl Pritchard, Ph.D., PMC Senior Vice President, Science Policy

As the stubborn pandemic exposes the shortcomings of the modern medical enterprise, clinicians and researchers are uncovering new insights about the challenges slowing the advance of personalized medicine. The field is rapidly evolving, but implementation of the tests and treatments underpinning personalized medicine has been inhibited by complex but surmountable health care policy and clinical integration barriers. To combat these challenges, more evidence is needed to demonstrate the clinical and economic benefits of personalized prevention and treatment plans to payers and providers and advise on the best strategies to provide access to personalized medicine.

In a letter published earlier this year to introduce PMC's *Research Program* for 2021, PMC Board Chairman and Quest Diagnostics Senior Vice President and Chief Medical Officer Jay G. Wohlgemuth, M.D., noted that "in brief, we need more evidence that personalized medicine works — that it can improve clinical outcomes while making health care more efficient and therefore less costly."

As shown in a landmark PMC-commissioned study published in March in the *Journal of Personalized Medicine* titled "A Quantitative Framework for Measuring Personalized Medicine Integration into US Healthcare Delivery Organizations," personalized medicine is now being integrated at measurable levels throughout the United States health system. Its implementation, however, is uneven and often not at the level necessary to assure all patients have access to the safest and most effective treatments. In an invited commentary for the journal *Personalized Medicine* published alongside Peter J. Hulick, M.D., who serves as the Director of the Mark R. Neaman Center for Personalized Medicine at NorthShore University HealthSystem, PMC has reported that provider institutions trying to implement personalized medicine are facing "challenges such as limitations in the availability of diagnostic tests and interpretation of results; limited access to targeted treatments; limited coverage and reimbursement for diagnostic tests and targeted therapies; and a need for greater awareness and education regarding rapidly emerging personalized medicine prevention and treatment strategies."

Convincing payers that available tests and treatments can deliver the field's promise of more effective and efficient health care has been a struggle. In a recent article that underlines how rapid advancements in personalized medicine have challenged the health care system, Joshua Cohen, Ph.D., who serves as an independent health care

"PMC's portfolio in science policy is focused on enhancing our understanding of PGx interactions, studying the clinical and economic benefits of personalized prevention and treatment plans, and advising health care providers on the best strategies for integrating the tests and treatments underpinning personalized medicine into clinical care."

analyst for *Forbes*, explains the difficulty of proving the real-world clinical utility of more than 75,000 genomic tests using only a few hundred available reimbursement codes. Many payers have concluded that the evidence-based applications for genomic testing are fairly narrow.

To help establish the clinical utility of personalized medicine in cancer care, PMC convened an expert roundtable consisting of a diverse group of health care stakeholders, including payers and clinical guideline developers, that sought to redefine our understanding of the clinical utility of genomic testing with attention to a wider range of individual and systemic benefits. The Coalition is also spearheading research that may underline a link between health systems' adoption of personalized medicine and improved clinical outcomes. With this modernized definition of clinical utility and evidence of improved clinical care, the health care community will be able to highlight the value of personalized medicine to payers and providers whose policies and practices shape the outlook for the field.

Nowhere is the need for establishing the clinical utility of testing more pressing than in the arena of clinical pharmacogenetics (PGx). The landscape for PGx testing remains fraught with differing perspectives regarding the classification of certain drug-gene interactions. In a comparative analysis recently submitted for publication in the *American Journal of Health-System Pharmacy*, PMC and a team of authors including Atrium Health Cancer Pharmacology and Pharmacogenomics Chair Jai N. Patel, Pharm.D., LabCorp Associate Vice President and Scientific Director for Molecular Genetics Annette Taylor, Ph.D., and Geriatric Oncology Consortium Medical Director Howard L. McLeod, Pharm.D., found wide incongruities between the drug-gene interactions that appear in the U.S. Food and Drug Administration's *Table of Pharmacogenetic Associations* and those that are referenced in widely consulted clinical guidelines published by the Clinical Pharmacogenetics Implementation Consortium (CPIC). The findings suggest that conflicting information about drug-gene interactions may deter clinicians from ordering PGx tests whose results would be difficult to interpret. A more consistent and standardized approach to interpreting PGx information would encourage more widespread usage of these hallmark personalized medicine tests, which are designed to help physicians prescribe and dose medications based on each patient's genetic makeup.

In brief, as PMC Board Chairman and Quest Diagnostics Senior Vice President and Chief Medical Officer Jay G. Wohlgemuth, M.D., wrote in a letter co-authored by PMC President Edward Abrahams earlier this year to introduce the Coalition's *Research Program*, "we need more evidence that personalized medicine works — that it can improve clinical outcomes while making health care more efficient and therefore less costly."

PERSPECTIVE ON PUBLIC AFFAIRS

'This is Bigger Than a Few Classes of New Treatments:' Embracing a Multi-Dimensional Future for Personalized Medicine

by Christopher J. Wells, M.P.A., PMC Vice President, Public Affairs

In recent years, personalized medicine has become almost synonymous in the public mind with gene and cell-based therapies that promise extraordinary downstream benefits, often for eye-popping prices.

These products warrant careful consideration. By altering the molecular makeup of a patient's own cells in hopes of eliminating the need for daily maintenance medications over the course of many years, they present an unprecedented value proposition to patients and society.

But when we zero in on only the opportunities and challenges associated with certain classes of genetically guided treatments, we risk missing the larger point of personalized medicine, which simply assumes that the more closely we can tailor each person's health care to the biological characteristics, circumstances, and values that affect our health, the better off we will be. Casting aside academic conversations about which interventions should be considered "personalized," we are fortunate to live in an era in which groundbreaking biomedical interventions are giving us unprecedented opportunities to make more sophisticated medical decisions, one patient at a time. These trends are making it increasingly important for health systems around the world to embrace tailored prevention and treatment strategies, whether we call it personalized medicine or something else.

Advancements in data science promise a future in which real-world insights are combined with information from clinical trials to better analyze the effectiveness of health care interventions for selected patient populations based on a broader range of data on each patient's environment and circumstances gleaned from documents such as electronic medical records, claims statements, and even data generated by wearables and mobile devices. Though the outlook for accomplishing this today is fraught with privacy concerns

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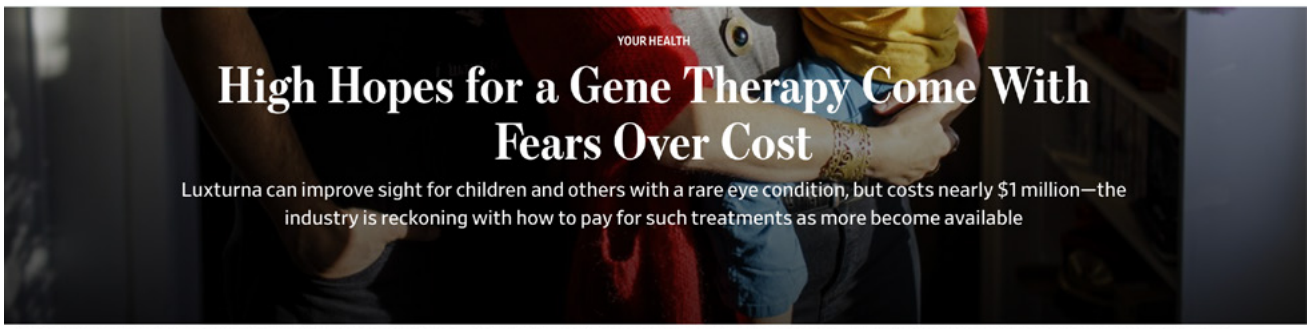

Caspian Soto plays with his parents, Krista and Zack Soto, at their home in Portland, Ore. Caspian, has a rare vision disorder and is among the first patients in the country to receive a new gene-therapy treatment. LEAH NASH FOR THE WALL STREET JOURNAL

In recent years, personalized medicine has become almost synonymous in the public mind with gene and cell-based therapies that promise extraordinary downstream benefits, often for eye-popping prices.

and data ownership questions, all but the most pessimistic observers anticipate a future in which we overcome these challenges with an eye toward leveraging advanced computing technologies and digitized data to improve patient care. When the data-driven era of medicine arrives, health systems will need to be well-positioned to take advantage of it.

Breakthrough discoveries in genetics anticipate the further alignment of medical decisions with patients' biological characteristics, including for patients with Covid-19. In a scientific article of extraordinary scope published in *Nature* on July 8, researchers reported that more than a dozen parts of the human genome are linked with either enhanced susceptibility to Covid-19 infection or an increased likelihood of severe Covid-19 symptoms. In discussing the significance of the findings with the *Boston Globe*'s health care affiliate, *STAT*, Nevan Krogan, Ph.D., who serves as the Director of the Quantitative Biosciences Institute at the University of California, San Francisco, took the science to its logical conclusion by noting that "where this is all heading is something that looks like precision medicine for infectious disease, where sequencing tells us both the genetic makeup of the patient and the virus infecting them, and that tells you which treatment to get."

Administrators and clinicians are also learning more about which patients may prefer telemedicine-driven health care delivery paradigms. In an article for May 20 that underlines how the COVID-19 pandemic has expanded the dimensions of personalized medicine, *NPR* documented how leading health care providers including Kaiser Permanente and the Mayo Clinic are continuing to embrace home-based hospital care paradigms that were originally developed to treat patients during the pandemic lockdowns. Margaret Paulson, D.O., who leads Mayo Clinic's home-based care program in rural Wisconsin, said the model has been especially well-received among "patients who have been in the hospital a lot."

These developments remind us that in an era characterized by a new understanding of what is possible in medicine, patients are counting on decision-makers in the public and private sectors to recognize the importance of a flexible health care delivery infrastructure that can serve diverse patient populations with wide-ranging needs and preferences. This is bigger than a few classes of new treatments.

MEDIA BRIEF

From the PMC News Desk

'Patients Don't Want to Be Cookie-Cutter:' *Vice* Magazine Spotlights Significance of PMC's Efforts to Break Mold of One-Size-Fits-All Medicine

An article published by *Vice* magazine on September 28 explores the significance of PMC's study about the potential of genomic sequencing to improve patient care and save money for health care systems by quickly uncovering rare genetic diseases that often require years of testing and hospitalizations to diagnose and treat. Published digitally on the popular lifestyle magazine's website, the article promises to help swell public support for research and public policies designed to break the mold of one-size-fits-all, trial-and-error medicine.

"Patients don't want to be cookie cutter," PMC President Edward Abrahams explained in the article.

See *Vice* magazine: "How Genetic Testing Will Create Personalized Therapeutics for Rare Diseases" (September 2021)

With Reference to Advocacy of PMC and ACLA, *Forbes* Explores Reimbursement Challenges Inhibiting Use of Genomic Testing Underpinning Personalized Medicine

With reference to the ongoing advocacy efforts of PMC and the American Clinical Laboratory Association, an article published in *Forbes* on August 13 explores how reimbursement and pricing challenges are inhibiting the widespread utilization of the genetic and genomic tests underpinning many personalized health care strategies. By spotlighting the difficulty of tracking the real-world clinical utility of more than 75,000 genomic tests using only a few hundred available reimbursement codes, the article underlines the need for innovative solutions to develop and analyze the data needed to facilitate evidence-based approaches to reimbursement for genomic tests with tremendous potential to improve patient care.

"While precision medicine has the capacity to revolutionize clinical practice, payers need to be on board with coverage of diagnostic tests in order to make this a reality," the article concludes.

See *Forbes*: "Genomic Diagnostic Tests Face Persistent Pricing And Reimbursement Challenges" (August 2021)

Part of PMC's *More Than a Number* Campaign, Article in *USA Today* by GO_2 Foundation for Lung Cancer Co-Founder Bonnie J. Addario Promises to Inspire More Lung Cancer Patients to Advocate for Access to Personalized Medicine

In a new article distributed in the *USA Today* on June 30 as part of an educational insert about the future of lung health, GO_2 Foundation for Lung Cancer Co-Founder and PMC Board Member Bonnie J. Addario outlines how the discoveries underpinning personalized medicine are transforming care for lung cancer patients. The article is part of PMC's *More Than a Number* initiative, through which PMC has partnered with Mediaplanet and the *USA Today* to bring its messages about the significance of personalized medicine to an audience of more than a million patients. The initiative promises to expand the number of patients benefitting from personalized medicine by inspiring more patients to ask questions about personalized prevention and treatment options.

"Upon being diagnosed with lung cancer, one question that should be at the top of patients' lists is whether their tumor has been sent for comprehensive biomarker testing and what the results are," Addario's article reads.

See Mediaplanet/*Future of Personal Health*: "Inside Personalized Lung Cancer Treatment" (June 2021)

During BIO Digital Session, PMC Board Members Lend Sense of Urgency to Efforts Focused on Facilitating More Equitable Clinical Integration of Personalized Medicine

During an Amgen-sponsored BIO Digital Convention session on June 16, Turna Ray, Managing Editor of *Precision Oncology News*, moderated a discussion in which a cross-sector group of panelists including PMC Board Members Lincoln Nadauld, M.D., Ph.D., of Intermountain Healthcare and Lauren Silvis of Tempus reflected on the status of efforts to translate the scientific discoveries underpinning personalized medicine into tangible benefits for patients. Despite a rapid pace of scientific progress, the panelists noted that the uneven adoption of personalized medicine among the United States' decentralized network of academic medical centers, integrated delivery systems, and community health centers is contributing to widening disparities in access to personalized medicine.

See BIO Digital: "Personalized Healthcare and Your Data: Improving Access and Addressing Disparities" (June 2021)

FDA Approves Targeted Cancer Therapy for Protein Once Thought 'Undruggable,' Spotlighting Personalized Medicine's Potential in Post-Pandemic Era

In a development that exemplifies how personalized medicine is expanding the scientific possibilities for treating cancer patients, the U.S. Food and Drug Administration recently announced the approval of a groundbreaking targeted therapy that inhibits the function of a cancer-driving protein once considered "undruggable." The approval of Amgen's Lumakras (sotorasib), which was reported in the lead story for the print edition of *The Wall Street Journal* on Saturday, May 29, promises to improve the outlook for personalized medicine by underlining its capacity for addressing unmet patient needs in the post-pandemic era.

See *Wall Street Journal*: "Amgen Wins Approval for Pathbreaking Lung Cancer Drug" (May 2021)

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