PERSONALIZED MEDICINE COALITION

August 2, 2024

The Honorable Diana DeGette
U.S. House of Representatives
2111 Rayburn House Office Building
Washington, DC 20515

The Honorable Larry Bucshon
U.S. House of Representatives
2313 Rayburn House Office Building
Washington, DC 20515

Sent electronically

Re: Cures 2.0 Request for Information (RFI)

Dear Representative DeGette and Representative Bucshon:

The Personalized Medicine Coalition (PMC), a multi-stakeholder group comprising more than 200 institutions and individuals from across the health care spectrum, thanks you for your continued efforts to advance *Cures 2.0* legislation. The preceding *21st Century Cures Act* made meaningful regulatory changes and provided essential support for many of the breakthroughs in personalized medicine that patients are benefitting from today. *Cures 2.0* legislation is necessary and has the potential to alleviate many of the obstacles still facing personalized medicine. We appreciate the opportunity to respond to your request for information (RFI) on *Cures 2.0* and to highlight outstanding issues that should be addressed by Congress.

Personalized medicine is an evolving field in which physicians use diagnostic tests to determine which medical treatments will work best for each patient or use medical interventions to alter molecular mechanisms that impact health. By combining data from diagnostic tests with an individual's medical history, circumstances and values, health care providers can develop targeted treatment and prevention plans with their patients.

Personalized medicine is helping to shift the patient and provider experiences away from trial-and-error treatments of late-stage diseases in favor of more streamlined approaches to disease prevention and treatment, which will lead to improved patient outcomes, a reduction in unnecessary treatment costs, and better patient and provider satisfaction. PMC's members are leading the way in personalized medicine and recommend that patients who may benefit from this approach undergo appropriate testing and tailored treatment as soon as possible during their clinical experiences.

Personalized medicine is delivering better efficacy, improvements in overall survival, and a reduction in adverse events for patients.[i] However, PMC has observed that the field continues to face challenges in delivering timely individualized care. Obstacles impeding the integration of personalized medicine are often caused when scientific developments outpace updates to our regulatory, coverage and payment, and health care delivery systems. In the current environment, patients, providers, and other health care

stakeholders are not always prepared to make informed decisions about personalized medicine based on an assessment of all available diagnostic and treatment options. We believe that *Cures 2.0* legislation is critical to help alleviate some of these challenges.

Statement of Neutrality

Many of PMC's members will present their own responses to the *Cures 2.0* RFI. PMC's comments are designed to provide feedback so that the general concept of personalized medicine can advance and are not intended to impact adversely the ability of individual PMC members, alone or in combination, to pursue separate comments with respect to this legislation or related issues.

PMC supports the important advancements noted in the RFI that have been made on issues such as:

- Improving our nation's response to future public health emergencies
- Advancing progress at the Food and Drug Administration (FDA) on critical issues, such as the emergence of cell and gene therapies
- Expediting drug approval processes and the integration of real-world evidence (RWE) in regulatory decision-making
- Clarifying coverage for some breakthrough medical devices

The RFI's first question asks whether policies that have advanced through other legislation or executive action meet the needs Congress aimed to address in the original *Cures 2.0 Act*. **PMC believes additional action on aspects of the 2022-introduced *Cures 2.0 Act* is necessary despite important advancements noted in the RFI. The following issues raised in Titles I - V of the *Cures 2.0 Act* are relevant today. In addition, PMC proposes some new issues for consideration as the *Cures 2.0* process moves forward.**

TITLE I: PUBLIC HEALTH

The COVID-19 pandemic was an unprecedented historical experience for the world that revealed vulnerabilities within our nation's health and security infrastructure that must be dealt with before the United States faces another devastating emergency. Leaders in personalized medicine worked rapidly to scale the United States' diagnostic capacity, develop treatments for patients suffering from COVID-19 infection, and develop vaccines, all while continuing to learn about individual responses to the SARS-CoV-2 virus and its variants. The COVID-19 public health emergency is over but the implications of COVID-19 must be understood and strategies for how we can better respond to future pandemics are necessary.

Sec. 101 of the *Cures 2.0 Act* called for a series of national meetings to serve as the basis for a COVID-19 learning collaborative with individuals and organizations representing key sectors of the health care community. **PMC supports the creation of this collaborative and a national testing and response strategy incorporating best practices for all test types, purposes, methodologies, and settings** called for in Sec. 102 of the *Cures 2.0 Act*. Sec. 105 of the *Cures 2.0 Act* would have provided incentives and pathways for the development of innovative antimicrobial drugs. These incentives and pathways are critically needed, as are the appropriate use plans developed by the Secretary of the Department of

Health and Human Services (HHS), infectious disease experts, diagnostics experts/developers, and laboratory experts to ensure the right personalized medicine diagnostics are utilized to guide drug selection or dosing.

TITLE II: PATIENTS AND CAREGIVERS

Diagnostic testing underpins personalized medicine. These tests can sometimes reveal genetic mutations that make some patients more susceptible to diseases than others. They may also uncover characteristics of cells and tumors, or the functional status of specific biochemical pathways, that can be targeted by available therapies. Due to our relatively advanced understanding of how genes influence human health, genetic and genomic sequencing-based diagnostics are the most commonly used tools in personalized medicine. In recent years, however, scientists have made notable progress in assessing biomarkers beyond the genome, such as proteomic and metabolic biomarkers.[ii] There has also been unprecedented progress in developing molecular imaging tools that are advancing personalized medicine. The enhanced predictability made possible by such tools may improve the diagnosis of disease and help guide physicians toward the most effective treatments. This can not only improve the rate of successful treatment, but also help to avoid unnecessary medical costs that result from trial-and-error treatment processes.

Health systems are still working on developing and adopting the procedures necessary to facilitate the widespread utilization of personalized medicine. For this reason, patients and their caregivers must educate themselves about the field and discuss it with their physicians. Because we are moving away from a "one-size-fits-all" approach to medicine to one that is based on the individual patient's particular characteristics of disease, it is important that patients collaborate closely with their entire health care team to develop prevention, diagnosis, and treatment plans. **PMC continues to support provisions in Secs. 201 and 202 of the *Cures 2.0 Act* that would fund educational programs for caregivers and require the Centers for Medicare & Medicaid Services (CMS) to solicit input on promoting greater health literacy**. We also urge the inclusion of content that helps guide patient interactions with physicians and their entire health care team in this era of personalized medicine.

Personalized medicine also depends on a diverse, equitable, and inclusive biomedical research enterprise to generate reliable evidence to inform health care interventions for all patients. Without representative biomedical research and clinical trials, some care may be delivered, and therapies prescribed, based on assumptions that have gone untested in patients from underrepresented populations, risking disease progression and exacerbating health disparities. PMC recently convened leaders from across the health care spectrum who are contributing to the development of research programs in the public and private sectors to uncover sociocultural, behavioral, and systemic factors that perpetuate inequities in research participation and outcomes.[iii] **Sec. 203 of the *Cures 2.0 Act* would broaden our collective understanding of strategies that can be adopted to cultivate a more inclusive biomedical research enterprise** by requiring updates from federal health agencies on efforts to improve diversity in clinical trials while identifying barriers to participation.

TITLE III: FOOD AND DRUG ADMINISTRATION

FDA serves as an important gateway for many breakthrough personalized medicine products entering the market. Various centers at FDA have responsibilities for evaluating medical products for their safety and efficacy. As personalized approaches to treatment and prevention have grown, new types of drugs, tools, and technologies using a patient's genetic and other personal health information have challenged existing regulatory frameworks and processes.

Digital health focuses on using digital technologies to monitor and provide relevant health-related data about individuals. These technologies include a rapidly expanding array of consumer products and wearables, as well as complex clinical care platforms.[iv] The collection of accurate digitized information that can be integrated with other data is essential to personalized medicine, and we were pleased to see it highlighted as a priority in the *Cures 2.0 Act*.

Innovations in digital health technologies (DHTs) and artificial intelligence (AI) approaches provide new opportunities to derive important insights from the vast amount of data generated by patients, which can help to individualize care. Over the last four years, FDA has released an action plan for innovation in medical device software using AI and machine learning (ML), held a public meeting to discuss the use of real-world data (RWD) generated from patients through DHTs, and published learnings from its pilot precertification program for medical device software. In 2022, FDA published a final guidance on the use of DHTs in clinical investigations and a framework for the use of DHTs in drug and biological product development. In May 2023, FDA published a discussion paper, *Using Artificial Intelligence & Machine Learning in the Development of Drug & Biological Products*, to foster a dialogue on the use of AI in medical product development. **We continue to believe that Sec. 301 of the *Cures 2.0 Act*, which requests a report to Congress on collaboration and alignment in regulating digital health, can further clarify pathways for internal and external stakeholders and strengthen agency partnerships focused on AI/ML and DHTs to inform FDA's approach to regulatory oversight of emerging technologies.**

The *21st Century Cures Act* recognized the cost, time, and complexity associated with the research and development of new medicines, calling for the incorporation of novel clinical trial designs. FDA released an RWE (real-world evidence) framework in 2019 and subsequently acknowledged that pragmatic and hybrid clinical trials, including decentralized trials conducted at the point of care incorporating RWE, can help clinical trials become more agile and efficient and can allow patients to receive treatments from community providers without compromising the quality of the trial or the integrity of the data collected. **Sec. 302 of the *Cures 2.0 Act* proposed grants for novel trial designs, like complex and adaptive trials, and other innovations in drug development that could further build the science in RWE, digital health technologies, and patient experience data.**

Sec. 304 of the *Cures 2.0 Act* would require HHS to report on how it will maximize and expand the use of RWE and establish a task force to develop recommendations on patient engagement in data generation that will support ongoing RWE activities at the FDA and across the federal government to foster technologies that will make data-driven health care a reality. With clear mandates, such as key

performance indicators demonstrating how FDA is using RWE for pre-market evaluation of drugs, biologics and devices, as well as the inclusion of representatives from health data organizations, researchers and other non-industry stakeholders generating RWE, **a report and task force called for in Sec. 304 could inform further FDA guidance development on RWE that includes not only its uses in clinical trials, but also the discovery of predictive and prognostic biomarkers and clinical decision support.**

We have suggested that, in addition to the grant program proposed in Sec. 302, FDA should accelerate the use of decentralized clinical trials by issuing guidance regarding digital technology issues, including the acceptance of decentralized clinical trials. Since the *Cures 2.0 Act* was introduced, FDA has drafted guidances on decentralized clinical trials and held a webinar on the rapidly evolving clinical trial landscape as well as the agency's current thinking on the conduct of decentralized clinical trials. **Sec. 310 in the *Cures 2.0 Act* would require FDA to hold a meeting to develop recommendations for adopting decentralized clinical trials.** This would be another positive step forward in bringing clarity around this innovative approach.

Thanks in part to a responsive regulatory agency, personalized medicine has seen steady progress in recent years. Cell and gene therapy is a fast-growing area of personalized medicine development. As of January 2020, FDA had over 900 active Investigational New Drug applications for gene therapies,[v] though only 37 cell and gene therapies have been approved.[vi] The scientific review of cell and gene therapies requires the evaluation of highly complex information and, thus, reviewers with highly specific expertise. By 2025, FDA anticipates it will be approving 10 to 20 cell and gene therapy products per year.[vii] Thus, FDA needs additional resources to bolster its workforce and keep pace with the growing workload. The agency has not received the appropriated resources necessary to do so. **Sec. 303 of the *Cures 2.0 Act* requires a report to Congress on the current state of cell and gene therapy regulation and foreseeable challenges for FDA, including the additional resources and authorities that may be necessary to efficiently review such products.**

To ensure that patients have access to personalized medicine, PMC advocates for flexible coverage policies and adequate payment rates for personalized medicine treatments, diagnostic tools, and technologies. PMC has been working to inform strategies that facilitate timely access to personalized medicine based on the value it provides to patients, the health care system, and society. Unfortunately, the process for seeking and securing patient access to some technologies, molecular diagnostic tools and treatments by CMS and private payers has been challenging. In some cases, inconsistencies in coverage and inadequate reimbursement have impacted patient access. Sec. 305 of the *Cures 2.0 Act* requires the establishment of a communication mechanism between FDA and CMS on breakthrough therapy drugs. Given the complexity of delivering many of these therapies to patients and the barriers created for reimbursement to hospitals and health care providers, we encourage the inclusion of representatives from CMS in any conversations to consider not only coverage for the drugs, but also diagnostics used to inform treatment as well as provider reimbursement for the true costs of care associated with the delivery of a breakthrough therapy. **In our previous comments on the *Cures 2.0 Act*, we called for Sec. 305 allowing FDA and CMS to share information with each other as may be appropriate to inform and coordinate such decisions while ensuring separate and distinct standards for market access and coverage, respectively. We further recommend that Congress provide additional**

funding to CMS' Coverage and Analysis Group (CAG) for CMS to make strategic investments in CAG's workforce, which is responsible for overseeing local and national coverage determinations and drug product coding requiring increasing technical and clinical expertise.

TITLE IV: CENTERS FOR MEDICARE & MEDICAID SERVICES

PMC is interested in additional opportunities to modernize coverage and reimbursement processes at CMS that could ensure patient access to personalized medicine. In recent years, CMS has made national coverage determinations for certain types of technologies, as opposed to making them on a product-by-product basis, such as for next-generation sequencing-based diagnostic tests used in advanced stages of cancer. In June of 2024, MEDPAC reported to Congress on how CMS considers coverage of software technologies.[viii] Given the rapid pace of innovation and the challenges in securing coverage and reimbursement for some such technologies, **we believe Sec. 401 of the *Cures 2.0 Act*, which calls for a Government Accountability Office (GAO) report to Congress on recommendations to enhance Medicare coverage and reimbursement for innovative health technologies, is necessary to identify opportunities to streamline the coverage process. Sec. 401 could be improved by defining "innovative technologies," to include, but not be limited to, cell and gene therapies, individualized therapies, clinical decision support and patient management algorithms and platforms, molecular imaging, radiopharmaceuticals, and biomarker tests. Furthermore, Sec. 405 of the *Cures 2.0 Act* would require the Secretary of HHS to submit a proposal to Congress on how to provide coverage and payment for digital alternatives to treatment, including wearables and digital applications and platforms.** Sec. 405 complements other regulatory proposals in the *Cures 2.0 Act* advancing digital health and would help prepare CMS for the future as patients assume a larger role in managing their own health care and are more informed by their ability to access their personal data, including their genomic information.

Despite the consensus that personalized medicine approaches have significant value, their implementation – and, consequently, patient access – across the United States is highly variable.[ix] Telehealth can improve patients' access to personalized medicine by making it easier for a patient to connect with a health care provider, including providers a patient would not normally have access to at their current health care institution, to discuss appropriate treatment and prevention options, which may involve diagnostic testing. Telehealth also has the potential to mitigate barriers that disproportionately impact individuals from minority, low-income, and rural communities, and may be especially helpful for individuals who have to travel long distances to a provider or may face logistical or other challenges to accessing care in-person, such as the stigma often associated with seeking mental and behavioral health care. Congress' temporary expansion of Medicare beneficiaries' access to telehealth services during the coronavirus public health emergency played a critical role in ensuring continuity of care for patients. **Sec. 403 in the *Cures 2.0 Act* would allow the Secretary of HHS to permanently expand telehealth flexibilities and remove Medicare's geographic and originating site restrictions, which require a patient to live in a rural area and be physically in a doctor's office or clinic to use telehealth services. Sec. 403 should allow for the reimbursement of audio-only telehealth visits when an appropriately qualified healthcare provider determines that a face-to-face or video telehealth visit would not be indicated to ensure high-quality care.**

PMC has strongly supported a pathway that would extend coverage for breakthrough devices immediately upon the date of FDA approval for up to four years. For devices addressing areas of unmet medical need, which may include diagnostic and screening tests underpinning personalized medicine, the newness of the device, and in some cases small patient population sizes, can create challenges to gathering the clinical evidence needed for coverage and reimbursement determinations, including age- and disability-related outcomes, subsequently increasing the time between introduction to the market and patient access. Unfortunately, CMS' Transitional Coverage for Emerging Technologies Pathway and legislation like the *Ensuring Patient Access to Critical Breakthrough Products Act* exclude clinical diagnostic tests. **PMC strongly supports Sec. 404 of the *Cures 2.0 Act*, which would codify a transitional coverage and payment pathway for breakthrough devices under the Medicare program, including for specified breakthrough devices that do not fall into a defined Medicare benefit category. Sec. 404 should also extend to breakthrough devices for treating indications *or informing treatment of* an indication to ensure that personalized diagnostics are included.**

Since 2017, PMC has supported legislative efforts to establish a demonstration project identifying ways in which genetic and genomic testing can be better utilized to improve patient outcomes. **Sec. 407 of the *Cures 2.0 Act* calls for an essential study and report by the National Academy of Medicine on how genetic and genomic testing may improve preventive care and precision medicine. We believe the study and report in Sec. 407 needs to be pursued and include clinical laboratories among the entities consulted in preparing the report**. **Sec. 407 in the *Cures 2.0 Act* also would have expanded access to diagnostic testing for pediatric patients with rare diseases through** the *Precision Medicine Answers for Kids Today Act*. Many rare disease patients, who are often on Medicaid, experience lengthy delays in receiving diagnoses and treatments necessary for their diseases. The *Precision Medicine Answers for Kids Today Act* was not enacted last Congress. As an interim step, **PMC joins with other stakeholders to request that you send a letter to CMS asking the agency to issue guidance to states on Medicaid coverage for pediatric genetic tests for rare diseases under the Federal Early and Periodic Screening, Diagnostic, and Treatment (EPSDT) benefit. We encourage you to include a provision in the next iteration of *Cures* legislation to require the GAO to study the disparities among states in the delivery of genetic services as part of the EPSDT program and to evaluate why patients are being inappropriately denied genetic testing services.**

Certain personalized medicine tests, called pharmacogenomic tests, predict which medications at which doses will be most effective and safest for individuals based on their genetic makeup and known drug-gene interactions.[x] This information can help guide the safe utilization of medicines for many health conditions, including drug selection and dosing. **Sec. 408 in the *Cures 2.0 Act* would provide Medicare coverage for pharmacogenetic consultations between a beneficiary's health care provider and qualified clinical pharmacists about their genetic or genomic information and the dosage, safety and efficacy of particular drugs, biologics or other treatments**. Given the important role of these and other tests in personalized medicine, **PMC continues to support Sec. 408 if expanded to include consultations with genetic counselors and pathologists. Furthermore, PMC recommends the addition of language facilitating the provision of information as part of "pharmacogenetic consultations" identifying the extent to which the consultant's recommendations are based on a drug's FDA-approved label or clinical guidelines.** FDA drug labels provide important information regarding drug selection and dosing, as do published literature in clinical guidelines. At times, this

information can be discordant. What is in the label and what is in the clinical guidelines need to be considered and consulted by the provider to make an informed decision.

Greater adoption of pharmacogenomic testing is imperative to reduce adverse drug events and ensure the most effective treatment selections and doses for patients. The *Right Drug Dose Now Act of 2024* would update the National Action Plan for Adverse Drug Events, educate healthcare professionals on the role of pharmacogenomics in patient care, update FDA's Adverse Drug Event Reporting System to receive information about pharmacogenomic interactions, and enhance electronic health records to more easily flag when a gene-drug interaction may need to be considered during the medication ordering workflows. All of this work is essential to advance the adoption of pharmacogenomic-informed care**. H.R. 7848, the *Right Drug Dose Now Act of 2024,* should be included in future *Cures* legislation**.

We continue to also strongly support adding text of H.R. 3876, the *Access to Genetic Counselor Services Act*, in its entirety to Sec. 408 or elsewhere in any updated *Cures* legislation. Pharmacogenetic consultations are only a portion of genetic counselors' role in delivering personalized medicine. Genetic counselors are specifically educated, trained and qualified to provide consultations about genetic tests and their appropriate uses and applications. They are also trained to help patients understand their genetic information and the implications of their genetic test results on their medical conditions, levels of health risk, and the health of their families. They help ensure the most appropriate genetic test is utilized, thereby assisting with identifying a genetic cause of a patient's disease or symptoms and enabling the use of personalized medicine, such as pharmacogenetics. There is no better way to ensure that appropriate and innovative genetic testing, and thus personalized medicine, reach Medicare patients than to add genetic counselors to the Medicare program. Medicare's lack of reimbursement for genetic counselors continues to create access and quality barriers to genetic services. Leveraging genetic counselors' expertise promises to improve patients' access to personalized medicine.

TITLE V: RESEARCH

Decades of research on the genetic and biological underpinnings of disease has made it possible to develop new personalized medicine treatments for cancers as well as rare, common, and infectious diseases. Scientific progress relies on contributions from multiple stakeholders across the research and development ecosystem. PMC believes the Advanced Research Projects Agency for Health (ARPA-H) operating as a distinct entity at the National Institutes of Health (NIH) has the potential to significantly benefit patients and the health care system by expediting the development and application of new personalized medicine technologies. With a unique culture and organization that embraces the risk of failure and fosters collaborations similar to those we saw with the Human Genome Project, ARPA-H is already supporting the creation of new infrastructure and platforms to speed the application of health breakthroughs for cancer and rare diseases.

In our previous comments on the *Cures 2.0 Act,* PMC highlighted concerns that funding ARPA-H could ultimately reduce appropriations to NIH for traditional basic and translational research. NIH investigator-led research generates fundamental knowledge about the molecular basis of a disease and points to pathways for developing new treatments and potential cures. Diligently investing in NIH

research is key to bringing us the foundation for a future in which every patient benefits from an individualized approach to health care. **The existence of ARPA-H should not result in any future reductions in NIH funding. PMC appreciates the considerations included in Sec. 501 of the *Cures 2.0 Act* that call for priorities and a budget process for ARPA-H that are distinct from NIH's centers and institutes. We encourage Sec. 501 to be carried forward in future *Cures* legislation.**

VI. Additional Issues

Personalized medicines have accounted for at least a quarter of new drug approvals for each of the past nine years.[xi] Medicare's drug price negotiation program could have an outsized effect in discouraging the pharmaceutical industry from bringing additional personalized medicines and expanded indications to the market. Multiple analyses, including those from the Congressional Budget Office (CBO), have called attention to the potential consequences of the Medicare drug price negotiation program, such as canceled research and development and disincentives to invest in small-molecule medicines and therapeutic areas that require incremental innovation.[xii, xiii, xiv, xv] ***Cures* legislation could prevent and correct for potential impacts of the drug price negotiation program on personalized medicine by including H.R. 5539, the *Orphan Cures Act*, to protect orphan products with designations for multiple diseases and conditions from negotiation, H.R. 7174, the *EPIC ACT*, to implement a single timeframe of 13 years for potential negotiation on small-molecule drugs and biologics, and H.R. 5547, the *MINI Act*, to set a timeline for negotiation at 13 years for genetically targeted treatments because of their similar therapeutic action as well as similar development and manufacturing timelines.**

Emerging and innovative screening modalities can further public health for all Americans and address health inequities by improving timely access to and compliance with United States Preventive Services Task Force (USPSTF) recommendations. The USPSTF aims to review and update existing recommendations every five years, though multi-year delays are common. With rapid developments in biomedical innovation, the current pace of USPSTF updates can cause significant lags in the adoption of new technologies. This gap and the impact it can have on medical innovation has been acknowledged by Congress. The Agency for Healthcare Research and Quality (AHRQ) is authorized by Congress to provide scientific, technical, administrative, and dissemination support to the USPSTF. AHRQ can only support the USPSTF in modifying its processes to more expeditiously respond to changes in evidence if it has additional resources. USPSTF also lacks genetics expertise and representation of some specialties contributing to the USPSTF's lack of prioritization of genetic-related evidence reviews**. PMC encourages an emphasis in future *Cures* legislation on the USPSTF. PMC joins other stakeholders in calling on Congress to require seats on the USPSTF for medical genetics and specialties with precision approaches to care, such as oncology, and we urge Congress to require USPSTF to establish a plan for timelier evidence review and publication of updated recommendations impacting personalized medicine.**

The underpinnings of value-based care depend upon participation across the care continuum, which should start with the appropriate utilization of laboratory testing tools to properly diagnose disease and select, optimize, and monitor treatment and disease progression. In 2019, HHS' Office of Inspector General (OIG) final rule on value-based care excluded laboratories from being participants and from

receiving safe harbor protections to the Anti-Kickback Statute (AKS). In contrast, CMS allows laboratories to participate fully under its corresponding value-based arrangement exceptions to the physician self-referral law (Stark Law) in recognition that laboratories "contribute to the value-based health care delivery and payment system by collaborating with other sectors of the healthcare industry to improve care, lower costs, and ensure that patients are receiving appropriate care." OIG's policy leaves laboratories in the position of accepting the risk of potential enforcement action under the AKS related to arrangements that are otherwise deemed to be low risk by CMS under its exceptions. The inclusion of laboratories is important to the success of innovative value-based models that support personalized medicine. **PMC joins other stakeholders in recommending that Congress work with OIG to reconsider its policy to exclude laboratories from being participants in value-based care models and from receiving safe harbor protections to the AKS.**

Conclusion

Thank you for continuing to work on *Cures 2.0* legislation and for considering our comments. PMC welcomes the opportunity to serve as a resource for you and your staff to ensure the legislation can support the ongoing development and delivery of personalized medicine products and services for all patients. If you have any questions about the content of this letter, please contact me at 202-499-0986 and cbens@personalizedmedicinecoalition.org or David Davenport, PMC's Manager of Science and Public Policy, at 804-291-8572 and ddavenport@personalizedmedicinecoalition.org.

Sincerely yours,

Cynthia A. Bens
Senior Vice President, Public Policy

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