Testimony of Dr. Ruben Mesa,
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Before the House Energy & Commerce Subcommittee on Health
***Hearing on "*The Future of Medicine: Legislation to Encourage Innovation and Improve Oversight"**
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Good morning. Thank you, Chairwoman Eshoo and Ranking Member Guthrie, for the honor of participating in today's hearing and discussing the important issues you are considering in this Committee.

I am Dr. Ruben Mesa. Cancer is a thief that steals from cancer patients and their loved ones both length of life and quality of life. Indeed, cancer steals cherished memories not yet made. I am the son of a father lost to lung cancer, the son of a breast cancer survivor, and I have dedicated my life's work to changing the devastating effects of cancer.

I am the Executive Director of the Mays Cancer Center at UT Health San Antonio MD Anderson in San Antonio, Texas. As the only NCI-designated cancer center in Central and South Texas, Mays Cancer Center provides leading-edge cancer care, propels innovative cancer research, and educates the next generation of leaders to end cancer in South Texas.

I am a hematologist oncologist and a leading research expert on a group of bone marrow disorders, called myeloproliferative neoplasms or MPNs, that often lead to leukemia. Over my career, I have been the principal investigator or co-principal investigator of more than 100 clinical trials, including research that has led to four FDA-approved cancer therapies since 2011. Today, Mays Cancer Center is providing access to nearly 200 cancer clinical trials to patients in our region. Clinical trials are not a luxury for patients but are essential to us being able to provide the very best care for the cancer patients of our region.

I serve on the National Board of Directors for The Leukemia & Lymphoma Society, whose mission is to cure leukemia, lymphoma, Hodgkin's disease, and myeloma and improve the quality of life of patients and their families. LLS has invested over $1.5 billion in cancer research since its founding, and LLS-funded research has been key to advancing 75 percent of the almost 100 blood cancer-related FDA approvals over the last five years.

I also have served in leadership roles within the American Society of Hematology (ASH), the American Association for Cancer Research (AACR), and the Association of American Cancer Institutions (AACI), and I was recently named to the NCI's Clinical Trials and Translational Research Advisory Committee (CTAC).

As you may infer from that background, I am dedicated to advancing new and better treatments for cancer and that only occurs not only through advances in understanding the science of cancer but also well conducted clinical trials. This is my life's work. And that is exactly why I am so passionate about the urgent need for greater diversity in the clinical trials on which patients and doctors make their decisions about treatment.

In all my years of experience as a physician researcher, I have seen firsthand the tremendous value of improving the diversity of the patients participating in clinical trials. Because breaking down barriers to clinical trial participation not only promotes health justice: It's good science.

I'll give you one example. The community served by Mays Cancer Center is roughly 5 million individuals, of which nearly 70 percent have Hispanic heritage. Learning about differences in a cancer therapy response (either in side effects or effectiveness) between populations by race, ethnicity and other factors can teach us important scientific lessons. For example, colleagues found that a genetic variant, near the estrogen receptor 1 gene, is associated with breast cancer risk in Latinas of indigenous origins and is absent in individuals of mostly European or African genetic ancestry. This genetic variant, which is associated with lower risk of developing breast cancer, could not have been identified in a study without Latina participants, illustrating the urgent need to ensure the diversity of research study cohorts. This discovery could lead to new treatments that could help both Latina and non-Latina breast cancer patients. The lack of diversity across clinical trials today and the systemic underrepresentation of certain groups weaken our ability to develop new therapies that improve on existing treatments—we miss the learnings like we found related to genetic differences in breast cancer.

If we want new and better treatments for cancer and other diseases, this is not a problem we can afford to ignore. As America becomes more racially and ethnically diverse, a clinical trial system that fails to enroll patients from growing demographics will not support the pace of innovation that will help us meet our potential. If we ignore this challenge, we will see trials that take longer and provide less reliable data. We will be less certain if a drug will help cure a certain group, or whether another group will have unexpected or severe side effects. And we will see more trials that fail to enroll enough patients to ever know whether a promising therapy is a breakthrough or not—and that potential breakthrough may very well go back on the lab shelf.

My message for each of you today is that we don't have to accept that future. In fact, you have the power to make reforms that will help ensure patients in every part of the country have access to the clinical trial care they need, while at the same time accelerating the development of new and better treatment options for patients for decades to come.

Before you today are a handful of bills aimed at tackling these big challenges.

The DEPICT Act, H.R. 6584, would make several important reforms. The DEPICT Act would require trial sponsors to incorporate Diversity Action Plans early in the trial design process to ensure that trials are built with all patients in mind. There is no one-size-fits-all plan to attract underrepresented groups to a trial. Instead, trial sponsors would look at the demographic groups that make up their intended patient population and then incorporate trial plans to recruit and retain patients from those same groups to ensure that trials don't fail to gather data that will shape how a treatment is used in the real world. Under the DEPICT Act, if a sponsor does not meet the targets it set for itself in its initial action plan, the missing data could be gathered through a timely postmarket study.

At Mays Cancer Center, we have seen the value of intentional efforts to recruit minority populations. Years ago, we found that very few clinical studies had a pre-determined plan for maximizing participation among ethnic and racial minorities. We also realized that the barriers to participation in trials have many factors including lack of awareness or trust in clinical trials, how the trial was designed, the eligibility criteria, the burden for patients to participate as it relates to travel or complexity of participation. So, we mandated that each new trial at the Mays Cancer Center put in place a Minority Accrual Plan (MAP) that includes enrollment projections and a demographic-specific toolbox with

strategies for clinical investigators to pull from to promote enrollment.[1] Since its inception in 2013, this planning process has helped at least 50 clinical trials per year with the goal of improving enrollment. Prior to its implementation, the enrollment of Hispanics into our interventional studies was 46 percent; now it is 56 percent. Accrual of Hispanics into interventional nontreatment studies has fluctuated over the years, but in 2017 it was 59 percent.[2]

Clearly, researchers need meaningful plans to recruit and retain diverse trial populations, and we need those plans to be incorporated into clinical trial designs at the earliest stages. Thoughtful, systematic approaches like our MAP program simply are not always top of mind for trial sponsors, and the DEPICT Act would hold sponsors accountable for doing the necessary work of ensuring underrepresented groups aren't left behind and examining all aspects of trial design and conduct to diminish barriers.

The DEPICT Act would also hold FDA accountable for modernizing trial rules that too often create additional barriers to trial participation. For too long, outdated FDA rules have encouraged the delivery of nearly all trial-related care at centralized academic medical centers. Yet, we know that the time and cost of travelling back and forth from a centralized trial site is a significant burden for many patients. This is a significant challenge for our center; our catchment area includes the whole of South Texas—an area roughly the size of Pennsylvania—where a patient might be up to 350 miles away. These many burdens have an outsized impact on patients with low incomes or who have hourly and shift-based jobs who have to weigh trial participation against the impact of lost wages, job insecurity due to inflexible work schedules, lack of childcare, and increased travel costs.

The good news is that FDA has begun to rethink the traditional trial rules that promoted centralized care. In March 2020, at the beginning of the COVID-19 pandemic, FDA issued guidance on conducting trials during the public health emergency.[3] This guidance allowed certain trial services to be provided at community health facilities or in a patient's home, including the ability to utilize telemedicine to screen possible participants and have interim toxicity evaluation visits, as long as precautions were in place to ensure reliable data. We have two years of experience under these new flexibilities, and it's clear that certain standardized services such as phlebotomy, traditional diagnostic imaging tests, and vitals checks can be provided safely and accurately by community providers in many cases. Making permanent these flexibilities would dramatically reduce travel and cost burdens on patients and reduce a key barrier to trial enrollment and retention. The DEPICT Act would require FDA to gather stakeholder perspectives on the flexibilities piloted during the public health emergency and publish a report detailing which flexibilities merit permanency. This is a simple step Congress can take to hold FDA accountable for modernizing rules and regulations that can reduce travel time and costs without sacrificing trial data.

Finally, the DEPICT Act would provide critical trial enrollment and education resources to community health care providers to break down the barriers between academic trial sites and the community providers patients trust. The bill includes providing federal grants directly to community health centers

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[1] Trevino, M. et al., *The Development of a Minority Recruitment Plan for Clinical* Trials, Journal of Community Medicine & Health Education, 23 August, 2013, https://www.omicsonline.org/the-development-of-a-minority-recruitment-plan-for-cancer-clinical-trials-2161-0711.1000230.php?aid=17134

[2] Mesa R., Ramirez A., *Overcoming Barriers for Latinos on Cancer Clinical Trials,* Advancing the Science of Cancer in Latinos [Internet]. 13 Dec 2019, doi:10.1007/978-3-030-29286-7_12

[3] U.S. Food & Drug Administration, *FDA Guidance on Conduct of Clinical Trials of Medical Products During the COVID-19 Public Health Emergency: Guidance for Industry, Investigators, and Institutional Review Boards*, March 2020, Updated August 30, 2021, https://www.fda.gov/regulatory-information/search-fda-guidance-documents/fda-guidance-conduct-clinical-trials-medical-products-during-covid-19-public-health-emergency

serving underrepresented groups—allowing them to hire and train trial facilitation staff and implement the IT systems necessary to seamlessly educate and enroll patients.

I cannot overstate how important it is to empower community providers to answer their patients' questions and help them navigate the process of understanding trial enrollment criteria, insurance coverage, financial assistance, and all the complexities involved in even a single trial. Research has shown that trial-skeptical patients in underrepresented groups are willing to give trials a fair shake if they can discuss all their concerns with a provider they trust.[4] In South Texas we have found including the family health expert—whoever is the "go to" person in the family, whether a nurse, pharmacist, physician, or even just a well-informed family member—along with the patient in these discussions is critical, even if this occurs through Zoom or telemedicine. And resources that help to build bridges between study investigators and community providers has the potential to encourage those providers to offer trials more often as a valuable treatment option for their patients.[5]

Another bill under consideration today, **the DIVERSE Trials Act, H.R. 5030**, would enhance the ability of trial sponsors to work with trial participants to decentralize trial services by leveraging technology to move certain activities into a patient's home. The DIVERSE Trials Act would clarify that sponsors can offer trial related digital technologies, transportation, lodging, and meals to trial participants without the threat of legal action.

In addition, the DIVERSE Trials Act would go a step further by directing FDA to work with its international counterparts to harmonize federal rules on decentralized trial designs. Harmonized regulations around the world are key to facilitating trials on rare diseases for which patient populations are so small that researchers need to conduct global trials simultaneously.

Another bill in front of the Committee today, **"Cures 2.0," H.R. 6000**, would promote the type of attention necessary to make progress in the effort to promote access to trials for underrepresented groups. Cures 2.0 would promote public awareness of trials as a treatment option, call on experts at the Government Accountability Office and within HHS to recommend actions that would promote diversity in trial enrollment, and make clinicaltrials.gov more patient-friendly.

Of course, there is no silver bullet for fixing the current lack of diversity in clinical trials. No single piece of legislation can finish the job and allow us to turn to other work. This effort will take sustained attention and a willingness to act intentionally. But the results would be life-changing: Improved outcomes for patients. More and better therapies proven to be safe and effective. More years for patients to be with their families, living full and healthy lives.

You can take real and meaningful steps today toward that future, and I hope you will.

Thank you again for the opportunity to share my thoughts. I look forward to answering any questions you may have.

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[4] Brown, F., et al., *Perceptions of Participation in a Phase I, II, or III Clinical Trial Among African American Patients With Cancer: What Do Refusers Say?,* Journal of Oncology Practice, 1 November 2013, DOI: 10.1200/JOP.2013.001039

[5] Ramirez, A., et al., *Clinical trials attitudes and practices of Latino physicians*, Contemporary Clinical Trials, July 2008, https://doi.org/10.1016/j.cct.2007.11.001