Questions for the September 18, 2025 Energy & Commerce Health Committee Hearing Record

Reponses by Dr. Diana Zuckerman, National Center for Health Research

The Honorable Mariannette Miller-Meeks (R-IA)

1. Even when a breakthrough medical technology is FDA-cleared or approved, patients in rural communities often wait years for coverage and access — especially when those technologies are not traditional drugs or devices, but software-driven innovations like autonomous artificial intelligence systems that bring specialist-level diagnostic care directly into primary care and other frontline settings.

What do you believe are the most effective steps Congress and CMS can take to ensure that these kinds of diagnostic and preventive innovations reach rural and aging populations more quickly — particularly when they improve chronic disease management, close care gaps, support earlier detection of disease, and reduce pressure on limited specialist capacity?

Response of Dr. Diana Zuckerman, President, National Center for Health Research

Thank you for your question. I agree with you that it is essential that rural and aging populations have access to innovative diagnostic and preventive devices that have the potential to improve chronic disease management, close care gaps, support earlier detection of disease, and reduce pressure on limited specialist capacity.

Let me start with your question regarding the most effective steps Congress and CMS can take to ensure timely access to innovative devices for aging populations. Our analysis of the 160 breakthrough devices that the FDA has already approved, classified, or cleared for market indicates that many have not been tested on patients over 65 (and even fewer on patients over 75) so it is not clear how safe, effective, or practical they will be for our aging population, regardless of where they live. For most of the breakthrough devices, there is no publicly available information about whether the devices were studied on older patients or not. Age matters because the invasive procedures needed for implanted devices and many other innovative devices are riskier for older patients. Complications of these procedures may require immediate medical attention that may be difficult for older patients to access, especially those in rural areas.

As a result, providers in rural areas as well as those in the rest of the country will be at the same disadvantage: they will need to decide whether to try the new diagnostic or treatment device on their patients without any clear evidence of the likely risks and benefits for older patients, especially those who are frail. However, the decision is even more difficult for health professionals who treat patients who live far from emergency medical care that would be needed if an implanted medical device or a complex software-assisted device causes an adverse event. All devices have risks, but relatively minor adverse events that

the manufacturer and the FDA consider manageable can become major medical emergencies if a patient lives too far from a medical specialist or medical facility that has the necessary equipment and expertise to respond quickly and effectively to early signs or symptoms of medical complications.

One way to ensure safe use by older patients and those in rural areas is for the FDA to require that breakthrough devices that are likely to be used for patients 65-80 be studied on patients in that age group, and that the label and instructions for those devices provide user-friendly information on possible safeguards needed for patients living in rural areas or other locations with limited access to relevant medical care. If Medicare is required to cover the cost of breakthrough devices, CMS should also require evidence that the devices are proven safe and effective for most Medicare-age patients, 77% of whom are 65-84. For breakthrough devices used for treatment, CMS should disseminate objective, easy-to-understand information to providers about recommended safeguards for patients who live in rural areas or other locations with limited access to the appropriate specialists or major medical centers

The Honorable Debbie Dingell (D-MI)

1. In your testimony, you spoke about the need for more evidence regarding the accuracy of multi-cancer early detection tests and the safety and efficacy of "breakthrough" medical devices.

How will drastic cuts to research funding affect our ability to strengthen our understanding of both topics?

Response of Dr. Diana Zuckerman, President, National Center for Health Research

Nancy Gardner Sewell Medicare Multi-Cancer Early Detection Screening Coverage Act

As you know, there are currently no multi-cancer screening tests that have been approved, cleared, or classified by the FDA. As a result, the only such tests that can be legally sold in the U.S. are lab-developed tests, since those are not regulated by the FDA. CLIA has some authority to regulate the labs that make these tests but does not regulate the tests that the labs sell.

PMA standards are much stricter than the other device pathways (510(k) and De Novo). Although some Members and witnesses at the September 18 hearing referred to the bill's coverage requirement that multi-cancer screening tests would be "approved" by the FDA, the wording in the bill is not limited to "approved" tests. Instead, the bill would also require Medicare coverage for any multi-cancer screening test that FDA "clears" (through the 510(k) process) or "classifies" (through the De Novo pathway), in addition to those (i.e. PMA devices) that it "approves." Since a cancer screening test that the FDA considers "moderate risk" and therefore eligible for 510(k) or De Novo review would be held to a much

lower standard than a "high risk" PMA device, FDA standards would allow more false positives and more false negatives for cleared or classified tests, compared to approved tests. However, the problems and financial and health costs associated with false positives (that would result in unnecessary testing and treatment) or false negatives (that would result in a potentially deadly delay in treatment) would be substantial for 510(k) and De Novo tests. Since the PMA pathway would require much greater accuracy, the costs of false positives or false negatives would be much less devastating to patients.

In addition, the 510(k) and De Novo pathways can't require post-market studies at the time they are allowed to be sold; in contrast, PMA approvals can immediately require post-market testing. This is when the drastic budget and staffing cuts that you asked about are important. Given the cuts at the FDA, including retirements of so many experienced FDA scientists, it would be unlikely that any multi-cancer screening tests that the FDA cleared or authorized would have the thorough review and post-market surveillance that Congress would want for a potentially life-saving multi-cancer screening test that Medicare is required to pay for. At the same time, research to improve cancer screening and treatment at NIH and other HHS agencies will also be limited by substantial cuts in research grants.

The biopsies and other invasive tests and procedures that result from false positive cancer screening results are often riskier for older patients, so the poor accuracy of multi-cancer screening tests is especially important for Medicare patients.

Breakthrough Devices

We analyzed the 160 breakthrough devices that the FDA has already cleared, classified, or approved. Most breakthrough treatment devices were cleared for market (using the 510(k) pathway) or classified for market (using the De Novo pathway), and for that reason most were either not studied in clinical trials or were studied in clinical trials that did not have a placebo, sham control, or other treatment comparison group to ensure that the device was effective. Pre-market studies are designed and conducted by the device companies or by researchers hired by the companies, so the **cuts in staff and research funding do not directly affect the studies being conducted, but they do reduce the likelihood of NIH funding research relevant to breakthrough devices as well as FDA's ability to carefully review any new breakthrough device applications in 2025 or in the future**. We have been told by former CDRH staff that even before the 2025 staff cuts, the FDA did not have enough subject matter experts on issues like AI, software, toxicology, biocompatibility, or other important areas of expertise to help reviewers decide if a device met FDA's legal requirement of "reasonable assurance of safety and effectiveness."

As a result, CDRH reviewers had to make those crucial judgments based on limited knowledge rather than on the expertise that was needed. In addition, CDRH has relatively few scientific staff to analyze adverse event reports or other post-market data to determine how well patients using breakthrough devices are faring in the real world. Electronic health records make such studies possible, but staff and funding have historically been unavailable for HHS staff to conduct those studies. Cuts in staffing and research funds at NIH and FDA have made that situation much worse.

The quality of clinical trial evidence is better for the breakthrough devices that went through the **Premarket Approval (PMA) Process**, but even in cases where the FDA has required post-market studies because of concerns about safety or effectiveness, the staffing and research cuts of 2025 make it almost impossible for the FDA or other HHS agencies to conduct post-market surveillance needed to ensure that these devices are as safe and effective in the real world as they were in the relatively short-term clinical trials that were the basis of approval.

Equally important, our analysis of the 160 breakthrough devices that are on the market indicates that for those that provide information about the age of the patients in the studies that were submitted to the FDA, many had not been tested on patients over 65 (and even fewer on patients over 75). Age is important in research on medical devices because the risks of invasive procedures (inherent with implants and many other medical devices) are greater for older patients, reducing the likelihood that the benefits of a device will outweigh the risks. **As a result, it is not clear how safe, effective, or practical these breakthrough devices will be for our Medicare population**.

For most of the breakthrough devices, there is no publicly available information about whether the devices were studied on older patients or not. Although clinical trials are required to be listed in the government website **clinicaltrials.gov** and to list their results there, some clinical trials cited in FDA documents on breakthrough devices were not listed on clinicaltrials.gov and most have not yet listed the results of the study. The ages of patients in the study and other crucial information about study results should be listed, so I hope you and your colleagues will consider reminding the FDA that all devices with clinical trials, and especially those that are given priority as breakthrough devices, be required to list their results before FDA grants approval or clearance. **Posting study results in clinicaltrials.gov should certainly be a condition of Medicare coverage as well, since it is already required by law.**