October 13, 2025

Re: Additional Questions for the Record - E&C Health Hearing on 09.18.2025

1. The name of the Member whose question I am addressing: The Honorable Mariannette Miller-Meeks (R-IA)

2. The complete text of the question I am addressing in bold:

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. a. 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?

(3) Answer to that question in plain text:

FDA approval is a major stumbling block to any patient trying to access a new or innovative therapy because a non-FDA approved therapy will not be covered by insurance, will not be recommended by doctors (as it is not standard of care) and will not be marketed by providers.

It takes 10 to 15 years for the FDA to approve a new therapy, assuming it is profitable enough for an industry group to lobby for it. That is too long a delay for many diseases.

One of the most surprising and disgraceful discoveries that I made as a patient is that the US, despite having by far the most expensive health care, has poor outcomes for most demographics. Even my US surgeons agreed that the US standard of care lags behind the rest of the world and I suggest that it is because of the burdensome and restrictive regulatory environment.

The cancer patients who obtain the best outcomes are those that can either access an exemption from the FDA process or can travel to a foreign country for treatment. I did both. Had I been in a rural area, I likely would not have been able to do either.

In the absence of a functional FDA, some states are taking matters into their own hands. Some states are now creating right to try programs that would allow physicians to prescribe non FDA approved therapies. Montana has recently expanded its right to try laws to allow

easier access. New Hampshire is taking a similar path. Congress could pre-empt the field and break the connection between FDA approval and a doctor's ability to try new therapies.

One additional bottleneck is the US Preventive Health Care Services Task Force, which advises the FDA on what tests to approve. The USPTFS to this day still opposes testing for pancreatic cancer. The USPTFS position is based on outdated information. One immediate action that Congress can take to improve access to rural and underserved communities is to abolish the USPTFS.