A Letter Is Not a Rule

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It is easy to read a letter from a senior senator and hear a new law. The language is urgent, the demands are specific, and the subject is health, which touches everyone. But a letter, however forceful, is no regulation, and the difference between asking an agency to act and the agency acting is not a technicality. It is the difference between a proposal and a rule that binds hospitals, suppliers, and patients.

The letter at issue was sent on October 2, 2026, by Senate Special Committee on Aging Chair Rick Scott to the Centers for Medicare and Medicaid Services Administrator Mehmet Oz. In it, Scott asked the agency to prioritize American-made medical devices and pharmaceuticals, to require domestic storage of patient data, and to exclude China-made equipment when a domestic alternative exists. More specifically, he urged the agency to bar China-made medical devices and equipment from federal programs when domestic alternatives are available, to require medical-device and service providers to store data domestically, and to prevent Chinese manufacturers from benefiting from the 50 billion dollar Rural Health Transformation Fund. Those are three distinct asks, and they deserve to be considered distinctly, because each would operate differently and each raises different questions.

The first ask concerns procurement: a preference for domestic products and an exclusion tied to country of manufacture and domestic availability. The second concerns data: where patient data handled by device and service providers is stored. The third concerns a particular fund: keeping specified manufacturers out of a new federal rural-health fund. Lumping them together would obscure what is actually proposed. A procurement preference is not the same as a data-storage rule, and neither is the same as a fund eligibility rule. Each needs its own justification and scope.

The letter also cites a United States Cybersecurity and Infrastructure Security Agency advisory concerning a Contec Medical Systems patient monitor, and it raises concerns about biometric and health-data collection by China-linked wearable-device makers. Those surveillance and exfiltration concerns are claims in the letter unless independently established for a specific product. That caution, stated in the source article, is central to any fair reading. A cited advisory about one product does not establish a finding about every product made in a particular country. A concern about data collection by some makers does not establish that every maker engages in the same practice, or that every device presents the same risk. Evidence is specific or it is not yet evidence about the thing being judged.

This is where the distinction between a request and a rule becomes practical rather than abstract. The letter does not itself create an operative rule for the agency. It does not establish that nationality alone proves a product-level security defect. It does not convert cited cybersecurity concerns into findings about every China-made medical device. If the agency were to act on the letter, it would still have to define which products fall within any exclusion, what counts as a domestic alternative, how availability would be determined, and what process a manufacturer or provider could use to contest a determination. None of those questions is answered by the letter itself, because a letter is an invitation to make policy, not the policy.

Consider the domestic-alternative test, because it sounds simple and is anything but. A device may have a domestic alternative in one category and not in another. An alternative may exist in principle but not in sufficient supply, not with the same features, not at a price a rural hospital can pay, or not with the same compatibility with existing systems. If the test is applied loosely, it could exclude equipment that hospitals still need. If it is applied strictly, it could become a loophole that swallows the exclusion. The hard work lies in defining availability in a way that is honest about supply, capability, and cost, and in updating that definition as supply changes. A slogan cannot do that work. A rule, written with definitions and evidence, would have to try.

Consider the data-storage ask on its own terms. Requiring domestic storage of patient data handled by device and service providers is a different kind of measure from a procurement exclusion. It is aimed at where data rests and who can reach it, rather than at where a device was assembled. A data rule of that kind could, in principle, apply across manufacturers, with requirements about access, encryption, auditing, and breach notification doing much of the protective work regardless of origin. It could also be drawn narrowly or broadly, with very different consequences for providers that rely on cross-border services. The point is not that a domestic-storage requirement is right or wrong in the abstract. It is that its merits depend on its technical design, and that design cannot be judged from a letter's summary alone.

Consider the rural-health fund ask as well. Preventing specified manufacturers from benefiting from a new federal rural-health fund is presented as a way to keep public money from supporting a perceived risk. But rural health programs are often the places with the thinnest margins, the fewest suppliers, and the greatest difficulty recruiting staff and maintaining equipment. An exclusion that is poorly defined could, in practice, reduce the options available to the very communities the fund is meant to serve. That does not settle the question against exclusion. It means the exclusion needs a clear account of which manufacturers are covered, on what evidence, and what alternatives will be available to rural providers on the day the exclusion takes effect.

Underlying all three asks is a question about inference. When is it legitimate to move from a documented risk in one product to a rule about a class of products, and when does that move become a blanket inference? The source article's assessment draws the line in a useful place: medical-device security should be governed by transparent technical evidence, enforceable data rules, resilient supply chains, and procurement standards that distinguish documented risk from blanket inference. Each element of that sentence does distinct work. Transparent technical evidence means findings that can be examined, tested, and challenged, rather than assertions that must be taken on trust. Enforceable data rules mean obligations with consequences, not aspirations. Resilient supply chains mean attention to whether domestic capacity actually exists before dependence on foreign supply is cut. Procurement standards mean criteria stated in advance, so that suppliers know what is required and buyers know what they are choosing.

Blanket inference fails on all four counts. It replaces examination with category. It treats an assertion about some products as a conclusion about all of them. It ignores whether alternatives are genuinely available. And it gives suppliers no clear standard to meet, because the standard, if it is only origin, cannot be met by better design, better testing, or better data practice. A manufacturer that improved its security could still be excluded if origin were the only test. That is not a security regime. It is a sorting regime, and sorting is a poor substitute for security.

None of this implies that concerns about device security or health data are trivial. A patient monitor that mishandles data, a wearable that collects biometric information without clear safeguards, or a supply chain that leaves hospitals dependent on a single foreign source for critical equipment are all serious matters. The question is how to respond to

them in a way that actually reduces risk. A response built on product-level testing, published findings, and enforceable data obligations targets the risk where it lives, in the device and in the data flow. A response built only on origin targets a proxy for risk, and proxies mislead whenever the proxy and the risk diverge, as they often do.

There is also a patient-centered reason to insist on specificity. Patients do not experience country of manufacture. They experience whether a device works, whether their data is protected, and whether their hospital can obtain the equipment it needs. A policy that excludes a safe, needed device because of its origin harms patients without making them safer. A policy that admits an unsafe device because of its origin harms patients while claiming to protect them. In both directions, the error comes from judging the label instead of the product. The remedy is the same in both directions: judge the product, publish the basis, and let the judgment be checked.

The role of the agency, if it takes up the letter, will therefore be more demanding than the letter itself. It will need to translate a political request into administrative criteria, to gather technical evidence product by product where product-level claims are made, to define domestic availability in operational terms, and to explain how data-storage requirements will be monitored and enforced. It will also need to hear from hospitals, manufacturers, and patient advocates, because each group holds information the agency lacks about supply, compatibility, and clinical need. That slower process is how a proposal becomes a defensible rule rather than a gesture.

The letter deserves to be taken seriously as a statement of concern and as a prompt for agency action. It does not deserve to be mistaken for the action itself. The serious response to it is to ask, for each of its three asks, what evidence supports it, what rule would implement it, what alternatives exist, and what safeguards would protect patients during any transition. Those questions do not dismiss the senator's concerns. They give those concerns their proper test, and a concern that survives that test emerges stronger, because it will then rest on evidence and criteria rather than on category alone.

A note on what this essay is not

This essay is not law and is not an official position until approved. It interprets a public letter and the source article describing it. It does not provide legal or medical advice, does not determine the status of any particular device or manufacturer, and does not create or change any agency rule.

What is still open

Much remains undecided on the record described here. The letter is a policy request, not current regulation, so whether the agency adopts any procurement preference, exclusion, or domestic-storage requirement, and in what form, is not yet known. The surveillance and exfiltration concerns raised in the letter remain claims unless independently established for a specific product, and no product-by-product finding covering every China-made device is provided in this record. How domestic availability would be defined, how any fund exclusion would be scoped, and what data-storage obligations would require in practice are also open questions that only a future agency action could answer.

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