

February 26, 2024

The Honorable Paul A. Gosar
The United States House of Representatives
2057 Rayburn House Office Building
Washington, DC 20515

Dear Congressman Gosar,

We are writing in response to your letter dated February 21, 2024, related to TransMedics, Inc. Your letter contained extremely serious accusations and we are responding to these accusations with the same level of seriousness and with factual evidence. Respectfully, we are very disappointed that you have been provided with inaccurate information about TransMedics and the transplantation system, which appears to have led to inaccurate conclusions.

TransMedics has established a long-standing reputation and track record of being a clinically driven, transplant focused, and transparent organization whose mission is “to become the trusted partner to transplant stakeholders worldwide, focused on delivering the highest quality technology, service, and clinical care to save patients’ lives”. We take this mission very seriously, and we have spent over 25 years dedicated to improving transplant outcomes and, most importantly, increasing the number of organ transplants for those patients suffering from end-stage organ failure in the US and around the world. Growing the number of organ transplants has been the goal of the US Federal government over the past 5+ years with multiple bi-partisan initiatives and a presidential mandate to increase the number of organs available for transplants in the US.

Our Organ Care System (OCS) technology and our National OCS Program (NOP) services have begun to meet this mission by allowing more organs to be transplanted in the US. The focus on increasing the number of organ transplants in the US is driven by two important facts; 1) Transplantation is a life-saving therapy, without it, patients die due to end-stage organ failure after incurring significant cost burden to the healthcare system; and 2) Transplant therapy has been proven to be the most cost-effective treatment for end-stage organ failure -- a disease state that costs the federal government hundreds of millions of dollars annually to keep patients alive. These are proven and published facts.

The use of TransMedics’ OCS technology and NOP service program have unequivocally led to a 12% increase in liver and heart transplantation in the US in 2023. These double-digit increases in liver and heart transplantation have not been witnessed for almost 8+ years. This statistic is demonstrated by publicly available data from the national US Organ Procurement and Transplant Network (OPTN). We have driven this increase by accessing and recovering



donor organs that are historically unutilized due to the limitations of cold preservation and limited logistics that prohibit access to distant donors. We are confident that this is only the beginning, and we fully expect to further increase the utilization of donor organs for transplants. We are also confident that increasing the number of transplants will continue to drive a significant economic savings to the US healthcare system. All stakeholders, including CMS and commercial payors, have a desire to increase the number of transplants to save lives and reduce overall costs.

While we appreciate the opportunity to address the issues raised in your letter, we cannot do so without noting that the hostile and accusatory statements in the letter suggest that you reached inaccurate conclusions based on misinformation and false statements from what appears to be a transplant logistics competitor of TransMedics. We are very disappointed that your office made no efforts to speak with TransMedics to validate these false claims or at least to understand the transplant environment before sending the letter. Importantly, we note that you also publicly released your conclusory letter to the Daily Caller and on your Twitter/X feed before allowing us the opportunity to respond to these unfounded accusations. This is troubling to us, given the reputational damage alleged against the hundreds of TransMedics transplant professionals, as well as the harm that could be caused to our partnership with major transplant programs, which will negatively impact patients in need for TransMedics' transplant technology and services. We are particularly concerned given that the letter is based upon inaccurate third-hand reports and unidentified allegations, none of which have ever been raised directly with TransMedics. Finally, your letter suggests an outdated misunderstanding of the current transplant process, and the recent national changes in transplantation and organ recovery over the past several years. We write below to set the record straight and share with you the facts.

In the next section of this letter, we will respond directly to the inaccurate allegations in your letter on a point-by-point basis:

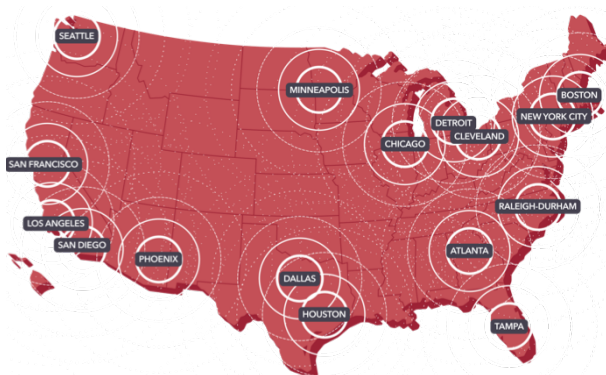
- Your letter asserted that TransMedics was selling our OCS device during the trial phase for \$30,000 and the disposables at \$7,000. This is not correct. TransMedics did not sell the OCS device during the trial phase, however, we sold the disposable OCS perfusion modules (cassettes) for \$45,000 per case during the trial period. CMS and commercial payors supported this approach throughout our trials based on the significant clinical and economic value of our product to: a) improve post-transplant clinical outcomes; and b) increase the availability of donor organs for transplantation that saves payors the significant costs of maintaining patients on the transplant waiting lists.
- Your letter asserted that once FDA approval was achieved, we mandated that hospitals that purchased the OCS device must meet a minimum volume. This is not correct. We did not mandate a minimum volume given that no hospital purchased OCS devices. The price change of the disposable perfusion module was fully expected by all transplant centers as it is common in the medical device industry post-FDA approval.



- Your letter asserted that TransMedics prohibited transplant centers from training their personnel on the OCS procedure. This statement is not correct. To-date, we have trained more than 400 transplant retrieval surgeons for heart, lung, and liver transplants across the U.S. Importantly, given our clinically focused mission, we are offering to train transplant fellows at academic transplant centers by our senior retrieval surgeons on how to perform OCS donor procurement surgery.

- Your letter characterized our NOP program as a means to reduce access to the OCS technology and increase prices and profitability. This is not correct. Contrary to the accusations in your letter, the NOP was developed for the exact opposite reasons and was based on direct feedback from major transplant programs across the US. The NOP program was created to:
 - Increase access to more donor organs across the US without the historical time and distance limitations imposed by old cold preservation techniques and local inefficient logistics networks;
 - Maintain the highest clinical standards of managing organs on the OCS system and significantly reduce the negative impact of learning curves on transplanted patients' clinical outcomes;
 - Reduce the fixed infrastructure and resources costs required of transplant centers to manage the OCS technology to access more donor organs and grow their overall transplant volume;
 - Avoid upfront investment by the transplant centers in technology capital equipment costs and transition into a more efficient cost structure that matches the transplant center's use of OCS;
 - Eliminate the technology cost burden of "dry runs" on transplant centers. Dry runs are the clinical situation of rejecting a donor organ after the procurement team arrives to the donor hospital due to clinical reasons or health status of the donor; and
 - Provide a better way to minimize fatigue and manage work-life balance of the surgical and clinical staff of the transplant centers.

To establish a more efficient model to deploy NOP and to maximize geographical coverage to access donor organs in a timely fashion, TransMedics invested in creating a first-in-class network of 16 NOP hubs, and growing, that included OCS technology, approximately 200 surgical and clinical personnel strategically located across the continental US to efficiently deliver this life-saving service across the country (see below).



Transplant centers had the option to either use NOP or continue to operate the OCS on their own by sending their own teams. Over the past 24 months, more and more centers elected to transition to NOP due to its more efficient cost profile, better clinical outcomes, and the ability to increase their transplant volumes without surgical fatigue of their staff.

The national success of the NOP program was featured and celebrated in the scientific sessions of the 2023 American Transplant Congress (ATC) in San Diego, the 2023 International Society of Heart, and Lung Transplantation in Denver and at the 2024 American Society of Transplant Surgeons (ASTS) meeting in Miami. Importantly, the success of the NOP has prompted many other transplant companies in the marketplace (XVIVO Perfusion and Paragonix) to create similar service models for their cold preservation technologies.

Similarly, the allegations of anticompetitive business practices are unfounded. Anticompetitive conduct, according to the antitrust laws, refers to practices that unfairly impede competition. None of these actions are practiced by TransMedics. We have always welcomed competition on the merits to ensure that patients in need are getting the best possible clinical services and there are numerous alternatives to the OCS system available and being used in transplantation today. In fact, if anyone is engaging in anticompetitive behavior, it appears that one of our competitors are propagating misinformation to unfairly disrupt TransMedics' business.

Your letter painted an inaccurate picture of the charter flight logistics for organ transplants in the US and accused TransMedics of creating a logistical network with newer aircrafts to unjustly increase cost on our clinical users. Again, this is not correct. Here are the facts.

- Historically, for cold preservation and organ transport, transplant centers relied on charter flight brokers and/or local small operators. These brokers typically have used what they promote as an "asset light model", meaning they don't own or operate any aircrafts. Their role is simply to contract a charter flight and a crew from local or regional operators when a donor mission is needed. When TransMedics first deployed the NOP program we too relied on this same network of charter brokers. Unfortunately, we quickly learned through firsthand experience that the brokered chartered flight model had significant limitations to help grow the transplant volume in the US and was becoming a huge bottleneck for our NOP program. This regional



charter brokerage approach was very operationally inefficient and added significant costs to the transplant centers due to:

- Fragmented local and regional operators using older aircrafts that were not capable of covering the new longer range donor missions now afforded by the new national organ allocation law in the US, the OCS technology and the NOP's capabilities to go longer distances to increase utilization of donor organs for transplants;
- Significant shortage of charter planes availability for 24X7 to cover the growing demand for transplant missions. This resulted in the loss of ~20-30% of donor retrieval missions in 2022 and early 2023;
- The lack of control over planes and pilots by most charter brokers often resulting in the use of more than one plane and multiple crews to complete a single mission -- which sometimes doubled the transportation bill paid by transplant centers;
- Lack of control over the starting location of the aircrafts, led to use of highly inefficient routes, which added even more costs in order to reposition the aircrafts;
- Lack of control over air safety standards of these contracted local or regional operators flying 20-30-year-old aircrafts. In fact, our NOP clinical and surgical teams experienced a few near-catastrophic events on brokered aircrafts in 2023;
- An inefficient round-trip cost model even if the donor organ is not procured for transplants or if a donor after circulatory death (DCD) never progresses to become a donor; and
- Finally, a very complex cost structure with multiple middlemen that paid, with associated profit margins, for the owner, the operator, and the broker of the chartered flight. All these added significant and unnecessary cost burden to the transplant centers

Reflecting these multiple challenges, the asset-light model (which had been the prior standard) has grown to represent a heavy financial and operational burden on the transplant centers. Importantly, it also limited the ability of the centers to grow transplant volumes due to shortage of dedicated aircrafts.

To address these significant inefficiencies, safety issues, and capacity constraints in the historical model above, TransMedics created a new, more scalable model that meets the current and future needs for growth of the transplant market in the US, while providing significant operational and cost efficiencies to the transplant centers. Our goals were to:

- Maximize donor organ utilization for transplants by building and operating a modern fleet of jets that can go longer distances. This fleet is dedicated to transplant missions and not charter flights. Using newer model aircrafts allows us to use less fuel so we can be environmentally responsible, reduce maintenance costs, and reduce downtime to maximize availability to conduct transplant missions;



- Maximize operational efficiency, which will reduce costs on the transplant centers;
 - Maintain the highest level of air safety for our staff, our clinical users, and the precious donor organs we are caring for;
 - Maximize logistics availability to ensure that we reduce the waste of donor organs that do not get used due to lack of plane availability; and
 - Leveraging the NOP network and modern dispatching algorithms to significantly reduce costs burden of DCD donors that don't progress to become a donor. The NOP network infrastructure created by TransMedics has given us a unique ability to share our cost efficiencies with the transplant centers.
- Your letter asserts that TransMedics uses aircrafts for non-transplant missions. This is not correct. TransMedics aircrafts are dedicated to transplant missions and moving NOP clinical/surgical staff and OCS technology to access donors in a safe, more reliable, and consistent fashion to maximize utilization of donor organs to help patients in the U.S.
 - Your letter accused TransMedics of pressuring hospitals to utilize our more expensive logistics. This couldn't be further from the truth. TransMedics presents the logistics quotation to transplant centers using our NOP service. The transplant centers then have the final say on whether they want to use our services or not. We are confident, given the above efficient way of operating our fleet, and our cost-sharing model with transplant centers that our quotes are lower than competitors who use the outdated brokerage model.
 - Your letter claims TransMedics' response to transplant centers was "not to worry, the American taxpayer will foot the bill through Medicare". This is another inaccurate statement. Our US transplant reimbursement team is highly experienced and fully versed in the reimbursement mechanisms for both CMS and commercial payors for transplants. In addition, we would like to point the following facts to further dispel this false allegation:
 - Approximately 30-35% of the US heart, lung and liver transplants are Medicare patients. The remainder are covered by commercial payors.
 - TransMedics does not bill CMS or any commercial payor for our products or services. The transplant centers are our customer. The transplant centers bill payors through standard organ acquisition mechanisms.
 - TransMedics prices have been shared with CMS and commercial payors since we launched the NOP, and many payors quote our pricing in their public presentations. We have not changed our pricing since then.
 - Finally, your letter cherry-picks a quote from a recent earnings call where we noted that transportation costs are reimbursed on the transplant hospitals' cost report as



required by law¹ and you insinuated that TransMedics was intending to ramp up transportation costs. In fact, the very next sentence in our transcript noted; “in fact, we are doing this because we could be more efficient and pass some of the efficiencies back to the transplant centers²”.

As we have described above, the serious accusations in your letter are simply unfounded. TransMedics is dedicated to transforming the field of organ transplantation to improve transplant clinical outcomes and, most importantly, to increase the number of transplants in the US and around the world. We are fulfilling this vision through the state-of-the-art OCS technology, the highest quality clinical service, and the safest and most reliable logistics operation. Our business is growing precisely because we are providing a better solution to the transplant community and not through any anticompetitive business practices.

Sincerely,

A handwritten signature in blue ink that reads "Waleed Hassanein". Below the signature, the text "PRESIDENT & CEO" is printed in a smaller, blue, sans-serif font.

Waleed Hassanein
PRESIDENT & CEO

Waleed Hassanein, MD
President and CEO
TransMedics, Inc.

¹ See 42 C.F.R. 413.402(b)(8) (specifically noting that costs associated with the transportation of the excised organ are to be included in the transplant hospital cost report and reimbursed by the Medicare program).

² See <https://finance.yahoo.com/news/transmedics-group-inc-nasdaq-tmdx-151529526.html>