STATEMENT FOR THE RECORD
Submitted by
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"The Long Haul: Forging a Path through the Lingering Effects of COVID-19"
Hearing before the Subcommittee on Health
Committee on Energy and Commerce
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Chair Eshoo, Ranking Member Guthrie, Chairman Pallone and Ranking Member McMorris-Rodgers:

Thank you for the opportunity to submit testimony today; I commend you for your foresight in scheduling this timely hearing on one of the most critical issues facing medicine and our health care delivery system today: the impact on patients and their care of long-COVID-19, or as some call it, "Long-COVID," or Post-Acute Sequalae of SARS-CoV-2 infection ("PASC").

For purposes of my testimony today, I will discuss PASC using the language NIH Director Francis Collins, M.D., Ph.D. put forward when he announced their new initiative to study "Long-COVID" on February 23, 2021. Dr. Collins said "I write to announce a major new NIH initiative to identify the causes and ultimately the means of prevention and treatment of individuals who have been sickened by COVID-19, but don't recover fully over a period of a few weeks.[1]"

I am Dr Rajarshi Banerjee — perhaps more easily known as "Banjo" — a medical doctor, scientist and co-founder of the United Kingdom-based company Perspectum; we deliver cutting-edge digital technologies that help clinicians provide better care for patients with liver disease, diabetes and cancer. With a strong focus on precision medicine using advanced imaging, Perspectum's vision is to empower patients and clinicians to achieve optimal health through quantitative assessments of health enabling early detection, diagnosis and targeted treatment.

In my testimony today, I wish to commend five important points to you for further study.

A brief mention about my background may help you put my remarks in context. I studied medicine at Oxford, and became interested in acquired heart and liver disease, which were alarmingly on the rise driven by obesity and alcohol use, conditions which are unfortunately all too present in the United States as well. I aim to improve care for these patients through earlier, safer and better diagnosis of their conditions using state-of-the-art, scalable scanning technology, enabling more speedy treatment and thus better outcomes. This led me to build a medical technology company, assemble a highly capable multidisciplinary team with many great diagnostic scientists, engineers and clinicians, and direct our focus to work on these challenges, starting first with liver disease.

As a company, Perspectum is committed to charting the uncharted in matters of public health and health care – and it became obvious to me early last year that we needed to focus our

[1] [https://www.nih.gov/about-nih/who-we-are/nih-director/statements/nih-launches-new-initiative-study-long-covid]

energies on the emerging public health challenge of our lifetimes: COVID-19. We quickly pivoted from our work focusing primarily on liver disease to research on the effect of COVID on internal organs using a holistic, scalable approach. We use one MRI scan at once of several organs, rather than multiple scans/visits as additional organ involvement might be suspected. Our products enable consistent, high-quality decision support to anyone with access to compatible MRI equipment, and empower patients to engage in the management of their health. Our advanced technology provides the metrics around which a better, more in-depth analysis of the location and extent of disease can be easily discovered.

The long-term impacts of COVID outside the lungs were not known in the period of March–April, 2020 when COVID first was discovered, so we undertook the world's largest study of mapping organ health in "post-COVID" individuals. This was before "long-COVID" was named that May in a tweet and then the phrase was picked up by patient advocacy groups. We built a medical device that could use existing MRI scanners coupled with our advanced software services to look at multiple organs in the torso, using a single 30-minute scan to find out if a patient has sustained organ damage from COVID.

It was not known if organ damage occurred in patients who had not been hospitalized, and we set out to study this. Our preliminary figures indicated that four to five months after infection almost 70 percent of COVID patients with persistent symptoms have sustained damage to one organ, and a quarter of these have two or more organs damaged. [2] The findings mirror another UK study which looked at 58 patients who had been hospitalised (so they were generally more severely affected in the lungs than the patients in our study).[3] At two to three months from disease onset, the study reported that MRI scans of COVID-19 patients post-hospital discharge revealed abnormalities in the lungs (60%), heart (26%), liver (10%) and kidneys (29%).

In January 2021, Perspectum received authorisation from the UK's Medicines and Healthcare products Regulatory Agency (MHRA) for special use of the service we developed to monitor post-COVID patients in the UK. Our service was cleared by UK regulators[4] for the benefit of public health with an exceptional use authorization, and we are now in discussions with your FDA to determine the best pathway to move forward.

Point one I wish to emphasize to you is that long-COVID must be treated seriously, because in the majority of persons whose COVID does not resolve in three months, there can be significant organ damage which should be treated early.

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[2] 'Multiorgan impairment in low-risk individuals with post-COVID-19 syndrome: a prospective, community-based study'
(https://bmjopen.bmj.com/content/11/3/e048391)

[3] 'Medium-term effects of SARS-CoV-2 infection on multiple vital organs, exercise capacity, cognition, quality of life and mental health, post-hospital discharge'
https://www.thelancet.com/journals/eclinm/article/PIIS2589-5370(20)30427-2/fulltext

[4] https://www.medsci.ox.ac.uk/research/networks/national-consortium-of-intelligent-medical-imaging/news/world2019s-first-integrated-imaging-service-for-long-covid-approved-by-uk2019s-mhra/

This brings up the next point I wish to commend to your attention and this is somewhat intuitive but not often recognized. Long-COVID is a multi-system illness that must be treated holistically. The health care delivery system must recognize at the outset that a person who has had COVID can sustain organ damage, often in multiple organs. Some physicians have dismissed patient concerns as anxiety, or psychological. Those treating patients initially must have a broad conversation with their delivery system peers so that a patient presenting with, for example, fatigue and breathlessness is also assessed for heart, liver, spleen, pancreas and kidney. This is not necessarily happening now.

As an aside, you might ask why I stress the compunction to treat early? Not only is the old adage true here – an ounce of prevention worth a pound of cure – but being aware of potential organ damage is something a COVID or former-COVID patient should know. For example, we know from UK data that the risk of death in patients who have been hospitalized with COVID is **8x higher** that than those in matched control groups (Ayoubkhani et al, BMJ 2021[5]), and the risk of readmission is over 30%, mainly with cardiac presentations (arrhythmia, infarction, cardiac inflammation, heart failure).

Today, there are not enough multisystem physicians -- such as internal medicine specialists and infectious diseases physicians -- to manage COVID patients who have damage in one or more organs. Single organ specialists are not able to look at these patients efficiently. We all recognize that it is hard to change our health care delivery systems, but change is essential, starting with medical school education.

This brings me to my third point. We have no idea how long long-COVID can persist in a patient. We are operating in real time here. It is entirely possible COVID-19 could engender a whole new cohort of the disabled – the UK Department of Health is currently considering whether long-COVID patients should qualify for disability benefits, for example. From UK longitudinal data of long-COVID patients, we know many long-COVID patients improve somewhat over 12 months, but even so many are not able to work for **months**. We have no way at present to predict how long a long-COVID patient could be ill. This is one reason Perspectum is working so closely with the patient community to keep a watchful eye on the progression of this disease and its impact on patients. It is likely we will have a whole new cohort of disabled patients of working age whose illnesses are the result of COVID-19. The Committee should keep this in mind when continuing its study of long-COVID.

The next point I wish to commend to Members is that we are beginning to see signs that health care delivery systems cannot keep up with the growing need for patient treatment. I recommend that your study of the long-COVID issue extend to the impact on the health care delivery system and how it can be improved for long-COVID patients who need access to treatment. Your NIH, more so than our counterpart in the UK is using patient expertise to prioritise the research agenda effectively. Perspectum is proud to be collaborating with Survivor Corps, a fast-growing and extremely dedicated grassroots movement connecting, supporting, educating, motivating and mobilizing COVID-survivors to support all medical, scientific and

[5] https://www.bmj.com/content/372/bmj.n693 - a study of all the UK patients hospitalised with COVID in our first wave, cataloguing their clinical outcomes and readmission rates.

academic research. Our dialogue with Diana Berrent, herself a long-COVID survivor, who founded this advocacy group convinces me that there needs to be a systemic review of services long-COVID patients can receive from providers such as Community Health Centers and Federally-Qualified Health Centers, and then determine where there are gaps that should be addressed to help long-COVID patients in need. For example, MRI machines are not readily available in all areas, such as rural locations. The cost of the machine and also the cost of services can be barriers -- as can reimbursement – and, as a matter of cost containment, many states also have restrictions on the numbers of diagnostic systems that can be in operation.

In certain locales, specialized clinics operated by hospitals and other community entities are springing up to help long-COVID patients with their health care need. I want to take this opportunity to applaud a helpful step the Department of Health and Human Services took Friday when it announced nearly $150 million in grants to 100 health center "Look-Alikes" for several important purposes, including enhancement of health care infrastructure enhancement and services in local communities.

The Medicare, Medicaid, CHIP and other government programs are also vital. Even so, there may be gaps. We must recognize there are gaps, identify where they are, and prepare to address that. The Committee is especially well-positioned to conduct such an evaluation and propound needed solutions.

The fifth point I wish to emphasize is that there is not enough information known about the disproportionate impact of long-COVID on certain patient populations, be it race, income, geography or pre-existing illness to name a few. That is why we in the long-CID community are thrilled that Congress authorized the $1.15 billion in research at the National Institutes of Health. We commend you for this, and we commend NIH under the leadership of Dr. Francis Collins for their foresight with and attention to this illness. We have collaborated with prestigious universities in the States to submit applications for funding under these NIH Research Opportunity Grants announced on February 23, 2021. Use of our diagnostic technology will aid researchers as they seek to answer the many probing questions NIH proposes to answer through this and subsequent calls for other research which will include clinical trials to test strategies for treatment and recovery promotion.

As I have said, it is key that we begin to learn more about who long-COVID affects not only so we can locate and treat these patients, but so we can prevent illness if at all possible.

The Committee may find of interest the research results of a published study that I co-authored with Dr. Arun Sanyal of Virginia Commonwealth University and others using Perspectum's Liver*MultiScan* technology[6], which is authorized for use in the US as well as the UK. We examined underlying risk factors for COVID-19 and found that hepatic steatosis, or "fatty liver," rather than underlying obesity, increases the risk of infection and hospitalization for COVID-19. Those obese individuals who have fatty livers are most vulnerable to COVID, and we can diagnose and monitor them with community MRI and prioritise them for vaccine boosters in the future.

[6] https://www.frontiersin.org/articles/10.3389/fmed.2021.636637/full

In closing, Madame Chair and members of the Subcommittee, we at Perspectum are thrilled that you have the foresight to turn your attention to the vexing public health problem that is long-COVID. From our work over the past year, it is clear that there is much to be learned about PASC – how it can be diagnosed and treated earlier, how the health care delivery system can best respond to the challenges it poses, whom the illness targets, and how long it can be expected to last.

It is my hope that the benefit of our experience will help direct you as you move forward, and I remain available to provide the benefit of our expertise to you at any time.

Thank you for this hearing, and thank you for the opportunity to submit this testimony today.