**STATEMENT FOR THE RECORD**

Submitted by
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"The Future of Medicine: Legislation to Encourage Innovation and Improve Oversight"
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 continued opportunity to discuss with the Subcommittee Perspectum's views on the need and opportunities arising from the United States' commitment to modernizing biomedical research infrastructure to keep pace with the astounding and rapid developments which are occurring almost daily in science. As a scientist, medical doctor, and co-founder of a diagnostics company, Perspectum, I commend you for continuing to move forward on this package of bills which collectively attempt to bolster biomedical innovation in the United States and improve oversight of public health programs,

This will come as no surprise given our discussions with many of you, but I welcome the opportunity to urge that the Subcommittee devote substantial attention to examination of how research can improve the diagnosis, treatment and potentially even curative treatments for long-COVID-19, or as some call it, "long-COVID," or Post-Acute Sequalae of SARS-CoV-2 infection ("PASC").

While infection rates are declining for the Omicron variant of COVID-19, unfortunately we still see concerning reports about the lingering effects of this virus. It is important to recognize that long-COVID may have a substantial effect on public health for years to come, potentially leading to significant disability. Quite simply, we need to be prepared.

As a current reminder, I would like to submit for the record a Reuters article from March 4th in which a pre-Omicron Danish study of 152,000 people found that almost a third of those who tested positive for COVID-19 reported symptoms that linger between six and 12 months after diagnosis. This is a recent and compelling reminder of the potency of long-COVID.

https://www.reuters.com/business/healthcare-pharmaceuticals/almost-third-people-report-lingering-symptom-6-12-months-after-covid-19-study-2022-03-04/

At the outset of this hearing, I hasten to recognise Oversight Subcommittee Chair Diana DeGette and former Chair Fred Upton for their vision, foresight and determination in drafting

and advancing the CURES 2.0 legislation. Your hearing today, and that there are at last count 91 cosponsors of H.R. 6000 speaks volumes about it, not only the need for this bill, but also the overwhelming support it is receiving in Congress.

Indeed, it is important to recognise the achievement of the predecessor law, and at Perspectum we hail the Committee's persistence and leadership in drafting, pushing to enactment, and then monitoring implementation of the landmark 21st Century Cures law (P.L. 114-255), which has done so much to spur innovation in health care research, treatment, and delivery. Your deep commitment to improving the lives of patients is evident by this substantial work, and it is even more impressive that you are now working on the follow-on, comprehensive, CURES 2.0 bill.

Today, I would like to provide the Subcommittee with the benefit of Perspectum's views on long-COVID, a family of diseases to which we have devoted considerable energy from the start of the pandemic. We are keenly aware, and are especially heartened, that the authors recognise the importance of advancing knowledge of long-COVID by addressing it in the first section of the bill. It is my hope this legislation can be enacted this year and I offer my continued assistance to members and staff whenever needed.

**Who We Are:**

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 realized that I wanted to play a role in improving care for these patients and focused on developing customized solutions to deliver better outcomes to promote what we call in Britain, "kinder healthcare." 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.

Perspectum now is a leading commercial-stage, precision health company based in the United Kingdom with offices in the United States. Our approach to patient care draws on the expertise of the renowned physicians and scientists who lead our company, and we collaborate with world-leading experts on metabolic diseases, cancer, diabetes and other chronic diseases to push forward research. In offering advanced diagnostic solutions to doctors, we can support better decision-making, personalized care for patients, and better outcomes.

At Perspectum, we are very proud of our flagship product, LiverMultiScan, which has been cleared by the Food and Drug Administration for the non-invasive assessment and monitoring of liver disorders that may include nonalcoholic fatty liver disease (NAFLD) and non-alcoholic steatohepatitis (NASH), a severe form of fatty liver disease. LiverMultiScan is now being used in over 250 sites in the US, and is part of the Medicare and AIM pathways for the safer evaluation of liver disease, replacing liver biopsy. We have other FDA-approved products,

including those to support precision surgical decision-making for hepatologists and provide clinicians with highly-specific tools to monitor biliary diseases, such as primary sclerosing cholangitis (PSC).

As a company, Perspectum is committed to innovation and matters of public health and healthcare.

**Our Response to the Emerging Covid-19 Pandemic:**

The long-term impacts of COVID outside the lungs were not known in the period of March-April, 2020 when COVID first was discovered and then declared a pandemic. Perspectum already had many great medical innovation and clinical scientists, so it was only natural to focus our energies on COVID-19.

We undertook the world's largest study of mapping organ health in 'post-COVID' individuals. We enabled existing mobile MRI scanners on site at our main office 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 by a disease. We became the first to show that organ damage can occur in COVID patients even if they have not been hospitalized. Our preliminary figures indicated that, four to five months after infection, almost 70 percent of COVID patients with persistent symptoms had sustained damage to one organ, and a quarter of these have two or more organs damaged (Dennis et al. 2021, referenced below).

Compelled by findings of our recently published community-based clinical study (designed and conducted by a Perspectum team in Oxford and our collaborators entitled, "Multiorgan impairment in low-risk individuals with post-COVID-19 syndrome: a prospective, community-based study," Dennis et al. (2021). BMJ Open, 11(3), e048391[1]), we are continuing to explore the possibility that there are unique health issues facing women presenting with Long-COVID. Of the individuals in our community study, 71% were females and 19% had been hospitalized with COVID-19. Impairment in the liver, heart or lungs was associated with further organ impairment in 63%, 62% and 48% of individuals, respectively. I also currently serve as a team member of the largest clinical long-COVID study to-date called STIMULATE-ICP2 (Symptoms, Trajectory, Inequalities and Management: Understanding Long-COVID to Address and TransformExisting Integrated Care Pathways), led by University College London Hospitals NHS Trust and University College London. The 2-year study is designed to deliver the needed knowledge to scientists and clinicians to improve patient care and to inform policymakers, while collecting real-world data at scale.

**Real-Time Revelations:**

[1] https://bmjopen.bmj.com/content/11/3/e048391
[2] https://www.stimulate-icp.org/

The long-COVID communities of researchers, clinicians and patients are extremely gratified that Congress had the wisdom to provide $1.15 billion in funding to the National Institutes of Health for grants which will begin to answer the myriad mysteries of PASC, including whom it affects, for how long, and how they should best be treated.

From our work, we become more and more convinced about the need to devote additional resources to long-COVID – to help patients, to identify how best to treat the range of illnesses long-COVID embraces, and to determine the extent and duration of post-COVID illness, among many issues. Even now in our third-year of the pandemic and despite the best efforts of researchers and clinical medical experts, we still have not identified sound clinical treatment pathways for long-COVID patients, do not understand whom it affects and for how long, and are still addressing the PASC crisis in "real-time," while many people are also now dealing with the after effects of COVID-19 infections persisting.

As you may recall, as CEO, I submitted testimony to the April 28, 2021, Health and the Environment Subcommittee hearing on Long-COVID in which Perspectum observed five key points that must be considered in any on-going study of long-COVID:

1) In the majority of persons whose COVID does not resolve in three months, there can be significant organ damage which should be recognised early;
2) Long-COVID is a multi-system illness that must be treated holistically;
3) We have no idea how long it will persist in a patient, and this could engender a whole new cohort of the disabled, especially among healthcare workers;
4) We are beginning to see signs that the health care delivery system cannot keep up with the need for patient treatment; and
5) More information needs to be developed about the disproportionate impact of long-Covid on certain patient populations, be it race, income, age, geography or pre-existing conditions, to name a few.

These observations largely remain true today and this supports the focus of the Committee's examination of how to speed work on emergent scientific challenges such as PASC.

For the benefit of the Committee, let me take this opportunity to share our thoughts on how the long-COVID sections of the CURES 2.0 proposal could be strengthened.

**Comments on Sec. 101, "Further Understanding the Implications of long-COVID":**

We are enormously appreciative of the prominent and early long-COVID language included in the CURES 2.0 bill; it is to be noted that the authors obviously understand the importance of work to help patients in this area because you included as the very first section,

Sec. 101, language on the "Further Understanding the Implications of Long-COVID." It is that language on which we wish to make several recommendations as follows.

First, at the outset, we urge that efforts be undertaken to develop a common understanding of the definition of "long-COVID" – whether in this legislation or by some other administrative, congressional or other action. It is extremely hard to measure the extent of PASC or know how long to monitor its progression in patients as well as our success in addressing it, without a common understanding of what and how "long" long is. Understanding these things is of the utmost importance from the perspective of patients' physical and mental health. We note that the World Health Organization (WHO) recently published a clinical case definition of post-COVID. Although the WHO definition has been criticized by some as lacking, we concur with the motivation behind the WHO's action – that a lack of consensus on the time of onset and length of symptoms could impede our complete understanding of the extent and duration of PASC; this undoubtedly affects medical research and the utility of study results.

**Other recommendations on the specific subsections of Sec. 101: "Further Understanding the Implications of Long-COVID":**

**General Comment:** As a general comment on the purpose of Sec. 101, we believe that this is an important and certainly a necessary goal. We also appreciate that the implications of PASC are far from being identified totally. That said, we urge that the Committee move beyond "study" to action on long-COVID where possible and especially in clinical settings and care, as there are published data showing that patients with long-COVID are at higher risk of death, disability and rehospitalisation.

Perspectum respectfully suggests you have the opportunity to play a leadership role in strengthening the US government's response to long-COVID by broadening this language. For example, this could be accomplished by a sectional title change:

We suggest that the title embrace the notion of encouraging action on the range of issues associated with long-COVID, beyond the national coverage study. We recommend the Section 101 title read "Establishing a Framework for Priority Action on Long-COVID."

While there is substantial funding being devoted to long-COVID research, and more to come as funding for programs under the ARPA-H entity you authorize gets underway, even so there is need for us to act now where we can. The job is substantial, spanning all the public health agencies as well as the Social Security Administration and perhaps the Department of Labor (e.g., the Office of Disability Employment Policy and the Occupational Safety and Health Administration) and the Internal Revenue Service among others.

**Authority for New Coordinating and Monitoring Bodies:** For this reason, we respectfully request you consider establishing two coordinating and monitoring bodies. The first would be an inter-agency Task Force which will bring together all of the Federal

government's myriad agencies who address long-COVID. The second would be a new "Office of Long-COVID" established under the authority of the Assistant Secretary for Health (ASH) at the Department of Health and Human Services (HHS).

Virtually every public health agency is involved in PASC in some way, from the Centers for Disease Control and Prevention to the National Institutes of Health, but also agencies such as the Health Resources and Services Administration which we believe will play a growing role as the need for increased service delivery in this population becomes more evident.

Over the years, the ASH has played a leadership role in coordinating the government's response to health crises, for example with AIDS in the mid-1980s. So, this would be a natural home for such an effort. That said, if you determine a broader need exists so that programs in human services could also be embraced, a new office could be established at secretarial level.

While we understand the natural reluctance to create bureaucratic entities, in this case there is an urgent need for such a coordinating body, which can both provoke action and monitor the range of results. Likewise, such a need exists across government agencies. If there are concerns about the length of operations of these offices, they could be term-limited with the possibility for reauthorisation in the future.

**Sec. 101(a)**

Regardless of who is the lead in Federal governmental long-COVID efforts, we think there is a need for further understanding the implications of a number of issues associated with long-COVID beyond what is in your draft legislation.
Sec. 101(a)(1)

**Additional requirements for the study:** For the Survey, authors may want to direct the Department of Health and Human Services to study current funding and sources for coverage of long-COVID in both the public and private sectors; this would complement the current language which surveys patients only. Further, we suggest you consider providing guidance on how "large" the national survey is – to make certain it adequately reflects a range of geographic areas, including rural and urban, a range of age groups, young to old, and a range of persons from varying socio-economic backgrounds, races, and genders. Health inequalities have been highlighted by COVID-19 and apply to long-COVID patients as well.

**Additional topics for the study:** We also recommend that the draft go beyond assessing the broad topics of health care coverage, long-term care coverage, and disability coverage to address problems more specifically with factors such as:

*-Eligibility for coverage in these three areas:*

- *for primary care visits*
- *access to diagnostics,*
- *follow-up with specialists, and*

- *on-going care and rehabilitation needs, including support to return to employment.*

*-Eligibility for services based on issues such as lack of an initial positive COVID test (discussed much at the April 28 hearing); and,*

*-The need for a standardized definition of disability to ensure quick access to disability coverage.*

**Sec. 101(a)(2)**

**Survey Report:** We agree it is important for Congress to have an expedited report about the coverage survey; that said, it might be helpful to require that in writing, in the report, that the Secretary or his designee provide a description of who was surveyed when and where, and a discussion of the answers to the above questions we suggested you pose.

**Sec. 101(b)(1)**

**Learning Collaborative:** Page 4, lines 1-2, you may want to make clear that the representatives should be from key sectors of the health care community "who have expertise in long-COVID."

**Sec. 101 (c)**

**COVID Scientific Research for Children:** We heartily endorse the addition to the proposal of this authorization for NIH grants to research the long-term effects and treatments of COVID-19 in children. We are starting to engage in such research in the UK and welcome any future collaboration.

**Sec. 101 (d)**

**Study on Disparities in Long-COVID:** Additionally, we welcome this addition to the previous draft, which will authorize a National Academy of Medicine study on disparities in racial and ethnic minority groups on the diagnosis of, severity of symptoms, access to care, and treatment for long-COVID. As the pandemic progresses, we are finding such disparities more and more, and their identification can only improve diagnosis and treatment outcomes.

**Sec. 101 (e)**

**Education and Dissemination of Information with Respect to Long-term Symptoms of COVID-19:** As previously cited, we are concerned about the relative lack of attention given to managing long-COVID clinically, and therefore a public education program at HHS is very welcome. Likewise, dissemination of information to providers under this program is a welcome

addition to the bill, although we caution any such program must not only be flexible enough to provide information in as close to "real-time" as possible. The information dissemination must also embrace the full range of issues associated with PASC, including appropriate diagnostic tools and treatment options.

**Funding for Programs Authorized in Sec.101:** We are heartened that H.R. 6000 has now allocated specific authorizations for programs contained in this section, in contrast to the "such sums" authorization in the previous draft. This is an improvement. Additionally, we note the relative lack of public discussion and thus priority devoted to long-COVID compared with COVID itself. As we watch the real possibility that this pandemic will become endemic, there is not enough focus on the fact that long-COVID most certainly could linger.

**By-Pass Budget:** As you know, the National Cancer Act of 1970 provided a special authority that allows the National Cancer Institute to submit a "bypass" budget directly to The White House without Department review. The intent was to make certain that cancer research received what the scientific community felt was necessary, unimpeded by more political considerations. Given the importance of continuing PASC research, we suggest you might consider authorizing the HHS to submit a "bypass budget" for some or all of the long-COVID programs authorized in H.R. 6000. If there are concerns about this precedent, it could be time-limited.

**Potential Addition to Sec. 101:**

**NIH Report:** Given that the majority of long-COVID activities are currently taking place at the National Institutes of Health, and recognizing the large appropriation for those activities Congress provided to NIH, a good idea may be to consider requesting a brief-but-comprehensive biannual report (or some other patient-friendly medium) from the agency on its COVID research activities. While we would not want to divert NIH's work, it is important that the patients know what research is being undertaken and where should patients and their families wish to participate or learn more. Clinicaltrials.gov may be too specific and not easily navigable for these purposes.

**ARPA-H**

Let me also take this opportunity to commend you, Chair Eshoo, for your foresight in drafting H.R. 5585, the "Advanced Research Project Agency-Health Act," which also enjoys solid support with 57 cosponsors. I can think of no greater way to enhance the successes we are achieving in biomedical research and health care delivery than to incentivize projects that will transform medicine for the benefit of patients. The prospect of devoting considerable resources to high-risk, high-reward projects is exciting to medical researchers.

**Conclusion:**

In closing, Madame Chair and members of the Subcommittee, we at Perspectum commend your foresight in addressing our Nation's over-arching biomedical research

infrastructure, and in specific the public health problem that is long-COVID. From our work over the past two years, it is clear that there is much to be learned about PASC, but we must ensure doctors and other health care providers recognise and diagnose long-COVID early in a patient's illness. We also must develop clear clinical guidelines while simultaneously developing effective treatment pathways. I am outlining just a few of the many challenges our health care delivery systems face – and I fear we are losing precious time for many patients and their loved ones already. 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.