DEMOCRACY COLLABORATIVE

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Dear Member of the European Parliament,

I am reaching out on behalf of The Democracy Collaborative, a US-based think tank for a democratic economy where I lead our work on the health and pharmaceutical sectors.

We are closely following the new European Pharmaceutical Legislation process and we wholeheartedly support the creation of a European public R&D infrastructure on medicines, with its own mission and delivery capacity, as suggested by independent studies (including the 2021 STOA panel study, "European pharmaceutical research and development: Could public infrastructure overcome market failures?" available at: https://shorturl.at/aivBI).

As such, we were pleased to see that the Parliament, in its plenary session July 12th, approved the following recommendation in the report on the COVID-19 pandemic: Lessons learned and recommendations for the future (2022/2076(INI):

"605. Calls on the Commission and the Member States to create a large-scale, mission-oriented, public European health R&D infrastructure which operates in the public interest to manufacture medicinal products of health and strategic importance for healthcare, in the absence of existing industrial production, in order to support the EU to overcome market failure, guarantee security of supply and prevent possible shortages of medicines, while contributing to greater preparedness for facing new health threats and emergencies;"

We urge the European Parliament to confirm the position recently approved in the aforementioned report, and include this proposal in the new legislation. Such infrastructure would be crucially important in a global health perspective through collaboration with scientists and physicians elsewhere, particularly in low and middle income countries.

In fact, we are currently working with both Senate and House offices here in the United States on draft legislation to form a similar public, full-cycle drug development institution whose mandate goes far beyond that of the existing National Institutes of Health to include public-interest prioritization of R&D and public-interest use of all intellectual property related to subsequent inventions. We believe these proposals are mutually beneficial and would help assure far superior results for both our populations—and the world—in terms of access to medicines, innovation, and local economic development.

As such, we fully support the proposal for a European Medicines Facility (EMF), as proposed by the Rapporteur's draft concerning the new Regulation on medicinal products as for Article 40a:

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"Establishment and role of the European Medicines Facility
1. The European Medicines Facility ('EMF') is hereby established.
2. The main missions and responsibilities of the EMF shall be:
(a) setting out a long-term vision of health priorities in the public interest at a Union level in the form of a strategic roadmap with a number of specific purpose-led R&D projects; in the elaboration of the strategic roadmap, the EMF shall engage in transparent consultation with relevant stakeholders, including scientific communities, Union public health authorities, patient and consumer organisations as well as the relevant agencies established at Union level;
(b) establishing, as a priority, a portfolio of priority pharmaceutical R&D projects addressing at least the following therapeutic areas:
(i) the development of priority antimicrobials provided for in the 'WHO priority pathogens list for R&D of new antibiotics', specifically those listed as priority 1 (critical) or priority 2 (high), or PE753.550v02-00 52/109 PR\1288702EN.docx EN taking into account as a priority any equivalent list of priority pathogens adopted at Union level;
(ii) the development of medicinal products for high unmet medical needs as referred to in Article 70(1) of this Regulation and unmet medical needs as referred to in Article 83 of [revised Directive 2001/83/EC], in particular for conditions not sufficiently addressed by the private sector and where the private R&D pipeline is unlikely to deliver on medicinal products and therapies;
(iii) the development of medicinal products for which the private sector charges excessive prices and for which alternatives or generic alternatives are non-existent or unaffordable"

The proposed facility need not displace existing industry, but rather is a necessary complement to private sector pharmaceuticals in order to ensure the equitable access to medicines, and robust pharmaceutical markets. We do hope that the European Parliament will not miss the opportunity of a new approach to face the challenge of unmet medical needs.

The attached academic commentary lays out the main tenets of the US proposal for a public pharmaceutical R&D institute which has since been further developed in collaboration with our counterparts on Capitol Hill. We are happy to answer any questions you may have regarding our work and expertise in this area and we look forward to your response as to the EU legislation.

Sincerely,

Dana M. Brown
Director of Health and Economy
The Democracy Collaborative