



Drug Developers, Payer, and Health Plan Perspectives on Long COVID Definition

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Who is BIO?

- Trade Association based in Washington, DC
- Policy, advocacy and partnering organization supporting innovative biotechnology life science companies in Health, Agriculture and Environmental
- Over 1,000 companies from small pre-revenue to Fortune 100
- Companies developing novel therapeutics and vaccines comprise 90% of our membership
- Focus on legislative, regulatory and policy solutions that drive innovation for unmet medical needs and access for patients



Industry is working on treatments for key health effects of Long Covid

- Recent publications have helped better define the clusters of various Long Covid symptoms:
 - Cognitive
 - Pulmonary
 - Fatigue syndromes
 - Gastrointestinal
- Companies with potential solutions have been engaging with patients to better understand the most important symptoms
- The goal is to design clinical trials to alleviate specific conditions
- BIO has convened several meetings with companies developing or interested in developing treatments

Defining Long Covid

- Companies' interactions with the FDA have been complicated to date – lack of guidance and urgency make pursuing clinical trials difficult
- BIO suggests that Long Covid could be defined as a syndrome or set of possible symptoms
- This would help to guide how companies can conduct their trials – focused on treating a specific symptom or problem rather than a broader “disease” called Long Covid
- It would also help industry work with the FDA on cross-Agency guidance, clearer pathways for interactions with the Agency and patient-centered clinical trials for the different chronic symptoms