REGENERATIVE MEDICINE AND ADVANCED THERAPIES

Information on Workforce and Education

Why GAO Did This Study

The field of regenerative medicine and advanced therapies—including cell, gene, and tissue-based therapies—is evolving and interdisciplinary. Practitioners believe these therapies have the potential to revolutionize patient care and improve lives. The promise of such therapies to ameliorate, or cure, previously untreatable diseases and conditions depends, in part, on the existence of a robust, well-trained workforce.

The Timely ReAuthorization of Necessary Stem-cell Programs Lends Access to Needed Therapies (TRANSPLANT) Act of 2021 included a provision for GAO to study the regenerative medicine and advanced therapies workforce in the commercial and academic sectors. This report provides information on (1) the makeup of this workforce, (2) education and training for this workforce, and (3) current and future workforce and education and training needs.

GAO interviewed officials from the Department of Health and Human Services (HHS), and eight stakeholder organizations selected for representation across the occupational areas GAO identified for this work, as well as other criteria. GAO also reviewed related reports and job postings. Existing workforce and education data do not contain information specific to the regenerative medicine workforce. To quantify the number of stakeholders who made certain statements, "some" means two to four stakeholders and "many" means five to seven stakeholders.

What GAO Found

The goal of regenerative medicine and advanced therapies is to repair or replace damaged human cells, tissues, or organs to supplement or restore function. The field is developing therapies that go beyond existing treatments to address underlying causes of disease or provide cures for previously untreatable diseases and conditions. The regenerative medicine and advanced therapies workforce is generally reflective of the larger life sciences workforce, with individuals occupying a wide range of jobs across research and development, biomanufacturing, clinical care, and regulatory affairs, as shown below.

Examples of Regenerative Medicine and Advanced Therapy Occupations

Research and development	Biomanufacturing	Clinical care	Regulatory affairs
Occupation examples:			
• **Translational scientists and other research scientists** (biologists, chemists, immunologists, virologists, cellular therapy scientists, etc.)[a] • **Computational biology data scientists** • **Biochemical and other engineers**	• **Biomanufacturing associates or specialists**[b] • **Quality control/assurance associates or specialists** • **Field application scientists**	• **Medical technologists** • **Ancillary staff** (phlebotomists, social workers, etc.) • **Clinical staff** (oncologists, immunologists, hematologists, nurses, etc.)	• **Principal investigators** • **Regulatory affairs consultants** • **Clinical pharmacologists**

Source: GAO analysis of information from articles, industry reports, and interviews with selected stakeholders and federal officials. | GAO-23-106030

[a]Translational scientists take discoveries made in the laboratory, clinic, or field, and transform them into new treatments and approaches that help improve the health of the population.

[b]Biomanufacturing activities include the production of therapies using living cells.

Individuals working with regenerative medicine and advanced therapies would need postsecondary degrees appropriate to their area of work. For example, researchers would generally need science- and engineering-based degrees, and clinical occupations would generally need clinical and professional degrees. Further, stakeholders noted that many occupations would likely need additional specialized training, such as training in laboratory techniques, or medical fellowships in topics and practices specific to the field.

Many of the eight stakeholders GAO interviewed discussed shortages in the number of current and projected laboratory and biomanufacturing technicians to support the development of regenerative medicine and advanced therapies, as well as gaps in other positions, such as data scientists. Some stakeholders said that education for these technicians at the community and technical college level is insufficient to meet current and future workforce needs. In addition, many stakeholders noted that there is no nationally recognized education curriculum for the field. One of these stakeholders agreed that a core curriculum that reflects the diverse, interdisciplinary nature of regenerative medicine and advanced therapies would help support a competent, robust workforce.

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