



## **Principles on Personalized Medicine**

Scientific advances in our understanding of the molecular and genetic causes of disease offer opportunities to advance a new approach to healthcare. This new approach, personalized medicine, will allow healthcare providers to identify the most appropriate therapeutic intervention and/or dosage for an individual based on his or her personal bio-molecular characteristics, thereby maximizing clinical benefit and reducing the risk of side effects. Healthcare providers may also be able to identify a preventative measure that is particularly suited to a particular sub-population. Through personalized medicine, many health care interventions may occur much earlier and with greater precision than ever before.

In order to advance the development of personalized medicine, public policies must **reflect the scientific and clinical value that innovative technologies – diagnostics, therapeutics, preventive measures, and research tools – bring to patient care.** BIO urges that the following key principles be integrated into public policy:

- **Any regulatory approval processes and oversight mechanisms for personalized medicine products must be risk-based, transparent and predictable, and must ensure product safety, effectiveness, and accuracy.** Elements include:
  - A clear pathway that encourages early collaboration for the approval of therapeutics and companion diagnostics.
  - Modernized product development and approval pathways for innovative personalized medicine technologies.
- **Adoption of personalized medicine products requires reimbursement policies that reflect the value that those products provide to patients.**
- **Intellectual property protections that provide incentives for innovation should be developed and maintained.**
- **The federal government should maintain robust funding for scientific research to enable new discoveries in personalized medicine.**
- **The training and education of healthcare providers should be a priority so that personalized medicine innovations can be implemented and translated into clinical practice.**
- **Improvements in the healthcare information infrastructure are necessary in order to support effective implementation of personalized medicine.**