

BIO Staff-Level Policy Committees



Joining a BIO committee is the best way to shape our domestic and international policies, participate in public outreach, and stay informed. Committee participation is open to all employees of BIO member companies. Members may be involved in committees as much or as little as they want to be. Members participate in committee calls to speak up about issues that are important to them, or simply network with peers.

Why join?

Committee members have:

- Access to BIO staff experts with deep policy, regulatory, tax, investment, and legal expertise.
- The ability to help shape BIO's domestic and international policy agenda; and
- Breaking news and timely newsletters on issues of importance to their companies.

Membership

Full-time employees of BIO member companies are eligible to join committees. There is no limit to the number of employees a member company can have on committees.

Operation

All committees operate on a consensus basis. If a consensus position cannot be reached among members on a policy issue, BIO cannot take a public position on that issue. While multiple employees may participate on a committee, each member company participates as one voice, or one vote, on policies and issues that come before each committee.

Meetings

Regular committee meetings typically occur via teleconference on a weekly or monthly basis with occasional in-person meetings to discuss pertinent policy issues. Attendance is not mandatory.

Communications

BIO communicates with committee members via email, and committees meet via conference call.

Sign up today!

BIO members: contact biomember@bio.org to request to join a committee.

Not yet a member? Please contact info@bio.org to join today.

Questions

Contact biomember@bio.org with questions.

TABLE OF CONTENTS

| | |
|--|----------|
| HEALTHCARE: SCIENCE AND REGULATORY AFFAIRS | 1 |
| Regulatory Affairs Steering Committee (RASC) ¹ | 1 |
| Pre-Clinical Safety Committee (biosafe) ¹ | 1 |
| Drug Development and Review Committee ¹ | 1 |
| Life-cycle Management Committee ¹ | 1 |
| Manufacturing, Quality, and Distribution Committee ¹ | 2 |
| Pediatrics Specialty Committee ¹ | 2 |
| Rare Disease and Orphan Drugs Specialty Committee ¹ | 2 |
| Regenerative Medicines Working Group ¹ | 2 |
| Biosimilars & BsUFA (Science & Regulatory) Committee ¹ | 3 |
| HEALTHCARE: POLICY AND RESEARCH | 3 |
| Policy, Access and Reimbursement Committee (PARC) ¹ | 3 |
| State Policy, Access and Reimbursement Committee (State PARC) ¹ | 3 |
| HEALTHCARE: SPECIALTY MARKETS | 3 |
| Vaccines Policy Working Group ¹ | 3 |
| Vaccines Policy State Working Group ¹ | 4 |
| Biodefense Policy Working Group ¹ | 4 |
| Vaccines Regulatory Affairs Committee (VacRAC) ¹ | 4 |
| Antimicrobial Resistance (AMR) Working Group ¹ | 4 |
| Personalized Medicine and Diagnostics Working Group ¹ | 4 |
| Coalition for Epidemic Preparedness Innovations (CEPI) Working Group | 4 |
| Influenza Working Group | 5 |
| COVID-19 Therapeutics Task Force | 5 |
| COVID-19 Vaccine Task Force | 5 |
| FINANCE | 5 |
| Committee on Foreign Investment in the U.S. (CFIUS) Working Group ³ | 5 |
| Finance & Tax Committee ³ | 5 |
| GOVERNMENT RELATIONS | 6 |
| Federal Government Relations Committee ¹ | 6 |
| State Government Relations Committee, Health ³ | 6 |
| INTERNATIONAL AFFAIRS | 6 |
| International Advocacy Steering Committee ¹ | 6 |
| International Regulatory Committee ¹ | 7 |
| ALLIANCE DEVELOPMENT | 7 |
| Alliance Development Committee ¹ | 7 |
| LEGAL & INTELLECTUAL PROPERTY | 7 |
| Biopharmaceutical Law Committee ¹ | 7 |
| General Counsels Committee ¹ | 7 |
| Intellectual Property Counsel Committee ¹ | 7 |
| Security Committee ¹ | 8 |
| Technology Transfer Committee ^{1, 2} | 8 |
| COMMUNICATIONS | 8 |
| Cost & Value/Communications Committee ¹ | 8 |
| IAMBIO Branding Committee ¹ | 8 |
| MEMBER SERVICES | 8 |
| BIO Business Solutions Advisory Board ⁴ | 8 |

Healthcare: Science and Regulatory Affairs

Regulatory Affairs Steering Committee (RASC)¹

The BIO Regulatory Affairs Steering Committee (RASC) acts as a Steering Committee for all staff-level Science & Regulatory Committees and Working Groups. The RASC takes the lead or makes assignments to Committees and Working Groups on implementation of user fee agreements, including continuous engagement activities with FDA. The RASC develops and implements strategic BIO responses to scientific and regulatory issues that affect the ability of BIO's human healthcare focused companies to research and develop new medicines and biotechnology therapies, and to bring these products to market. The RASC responds to proposed regulations and draft guidance documents as necessary and holds liaison meetings with FDA to identify and discuss regulatory best practices. RASC workstreams also encompass initiatives that are outlined in PDUFA VI and 21st Century Cures.

Task Force:

- Microbiome Task Force

Pre-Clinical Safety Committee (BioSafe)¹

The Pre-Clinical Safety General Membership Committee (BioSafe) serves as a resource for BIO members and staff by identifying and responding to key scientific and world-wide regulatory issues related to the preclinical safety evaluation of biopharmaceutical products on an as needed basis. General Members can participate in various expert working groups, task forces and work streams related to the preclinical safety of biologics. BioSafe is led by an elected 17-person leadership committee (BioSafe LC) which meets regularly.

Task Forces:

- Specialty Biologics Expert Working Group
- Pharmacokinetic/Pharmacodynamic Expert Working Group

Drug Development and Review Committee¹

The Drug Development and Review Committee addresses issues around the use of innovative tools and methods being utilized in modern drug development and review and to promote acceptance of these methodologies by regulators. This includes, but is not limited to, developing comments and white papers, development or participation in workshops, and interactions with FDA, as appropriate. The committee will act as a steering committee for the associated task forces.

Task Forces:

- Digital Technology Endpoints
- Decentralized Clinical Trials/Remote Monitoring/Telemedicine
- Patient Focused Drug Development
- Natural History Studies

Life-cycle Management Committee¹

The Life-cycle Management Committee will initiate discussions on developing workstreams and potential task force formation to address: pregnancy registries; modernizing PMC/PMR data collection; patient centric labeling; and use of informatics for monitoring safety, evaluating efficacy, and demonstrating value to patients. This committee will act as a steering committee for the associated task forces.

Task Forces:

- Real-World Evidence
- Genomic-Health Data Correlations to Streamline Indication Expansion

Manufacturing, Quality, and Distribution Committee¹

The Manufacturing, Quality, and Distribution Committee proactively identifies issues, develops policy proposals, and provides responses to regulatory and legislative activities regarding biotechnology manufacturing. This includes, but is not limited to, developing comments and white papers, development of or participation in workshops, and interactions with FDA, as appropriate. The committee addresses FDA's current Good Manufacturing Practices, innovative manufacturing technologies, quality oversight, quality-by-design, inspectional and compliance activities, international harmonization of manufacturing requirements, anti-counterfeiting measures and initiatives, and protecting the security and efficacy of the drug and biologics distribution system.

Task Forces:

- Innovative Manufacturing Technologies
- Inspections and Compliance
- Accelerating CMC
- Cell and Gene Therapies

Pediatrics Specialty Committee¹

The Pediatrics Committee coordinates BIO activities around pediatric clinical research programs and seeks to minimize barriers to, maintain incentives for, and communicate the value of robust drug and biologic research in pediatric populations. Specifically, the group coordinates BIO's activities surrounding the implementation and reauthorization of the Best Pharmaceuticals for Children Act (BPCA) and the Pediatric Research Equity Act (PREA). The group also works with FDA and international regulators to promote appropriate harmonization of pediatric regulatory requirements. In addition, the Committee provides a venue for biologics companies to discuss best practices and lessons learned with respect to the conduct and regulation of pediatric clinical research and development programs.

Task Forces:

- FDARA Section 504
- Innovation in Pediatric Drug Development

Rare Disease and Orphan Drugs Specialty Committee¹

The Rare Disease and Orphan Drugs Specialty Committee provides a forum for BIO members with a particular focus on rare diseases to discuss BIO's major advocacy issues and policies in relation to the development and marketing of orphan products. The Committee is cross-functional, reviewing both FDA and development issues as well as market access and commercialization policies (including reimbursement). The Committee serves the important role of identifying and raising rare disease-specific issues to the PARC (see description below) and the RASC (see description above), and contributes to the development of BIO's perspective on issues within this space. Committee participants have diverse portfolios including legal, regulatory, health policy, and government affairs.

Regenerative Medicines Working Group¹

The Regenerative Medicines Working Group focuses on issues relating to regenerative medicines, including cell and gene therapies and gene editing. The Group aims to advance policy positions that support an adequate and flexible regulatory environment for the development of

regenerative medicines. These positions are utilized to inform BIO's advocacy and educational activities.

Biosimilars & BsUFA (Science & Regulatory) Committee¹

The Biosimilars & BsUFA Science & Regulatory Committee supports BIO's broader biosimilars advocacy agenda by coordinating with other committees to provide technical expertise in matters pertaining to the underlying science and regulation of biosimilar products.

Healthcare: Policy and Research

Policy, Access and Reimbursement Committee (PARC)¹

The Policy, Access and Reimbursement Committee (PARC) focuses on federal legislative and regulatory proposals regarding health reform and existing and future drug coverage, with particular focus in the Medicare and Medicaid programs, as well as other federal health care and drug pricing programs (e.g. 340B program, ACA exchanges, rebate programs). This committee develops positions to maintain and expand market-based delivery systems to ensure patient access to biotechnology therapies. Members of the committee review health reform and reimbursement issues from a variety of perspectives, including legislative, regulatory, economic, marketing, and public relations. Members of the committee meet routinely with government officials regarding legislation and agency regulations. PARC members also have the opportunity to join *ad hoc* working groups that focus more specifically on particular issues. All policy discussions and recommendations from these working groups are taken back to the PARC for further discussion and approval. These groups include, but are not limited to:

- Part B Working Group
- 340B Working Group
- Transformative Therapies Working Group.

State Policy, Access and Reimbursement Committee (State PARC)¹

The State Policy, Access and Reimbursement Committee (State PARC) focuses on state legislative and regulatory proposals regarding existing and future drug coverage and coding and payment within state and private markets, with particular focus on the health insurance exchanges and Medicaid. This committee develops positions to maintain and expand market-based delivery systems to ensure patient access to novel biotechnology therapies. Members of the committee review health reform and reimbursement issues from a variety of perspectives, including legislative, regulatory, economic, marketing, and public relations. The committee is responsible for submitting comments, and when appropriate, engaging directly with state legislators and regulators on issues related to state legislation and regulation.

Healthcare: Specialty Markets

Vaccines Policy Working Group¹

The Vaccines Policy Working Group addresses vaccine policy issues, with a primary focus on federal domestic issues, but also addresses select state-level issues as needed. The committee interacts with government policy-making bodies and non-government partners. Examples of government policy-making bodies include the Centers for Disease Control and Prevention (CDC), the Food and Drug Administration (FDA), National Vaccine Program Office (HHS/NVPO), the National Vaccine Advisory Committee (NVAC), and the Advisory Committee on Immunization Practices (ACIP). Issues that have been addressed or are being addressed include

implementation of the Affordable Care Act (ACA), vaccine financing, vaccine safety, influenza vaccine awareness, and policies to support vaccine innovation.

Vaccines Policy State Working Group¹

The Vaccines Policy State Working Group meets regularly related to specific states/issues. The Group was formed to address state vaccine financing issues, but now comprehensively addresses legislative, regulatory, and political issues related to vaccines at the state level, including vaccine financing, access, confidence, and science.

Biodefense Policy Working Group¹

The Biodefense Policy Working Group advocates for policies to facilitate the biotechnology sector's contribution to national preparedness, including federal funding for biodefense, biodefense procurement reform, authorized funding for advanced development projects, and strong federal pandemic influenza funding across an array of technologies to address near-term, mid-term, and long-term opportunities. Member companies include those developing vaccines, therapeutics, and diagnostics for use as medical countermeasures in the event of a natural, accidental, or man-made biological event.

Vaccines Regulatory Affairs Committee (VacRAC)¹

The Vaccines Regulatory Affairs Committee (VacRAC) addresses vaccine regulatory policy issues, with a primary focus on U.S and some international regulatory issues. The committee interacts with government policy-making bodies and non-government partners, such as the Food and Drug Administration (FDA), the Centers for Disease Control and Prevention (CDC), National Vaccine Program Office (HHS/NVPO), and the Advisory Committee on Immunization Practices (ACIP). Issues that have been addressed or are being addressed include implementation of the Food and Drug Administration Safety and Innovation Act (FDASIA), drug shortages, and the FDA review process for vaccines, among others.

Antimicrobial Resistance (AMR) Working Group¹

The Antimicrobial Resistance (AMR) Working Group is comprised of companies working on the development of novel antibiotics, antivirals, antifungals, vaccines, and therapeutics targeted for resistant pathogens and nosocomial infections. The Working Group addresses issues related to infection control, antimicrobial resistance (AMR), and incentives for both antimicrobial and vaccine development.

Personalized Medicine and Diagnostics Working Group¹

The Personalized Medicine and Diagnostics (PMDx) Working Group identifies barriers and challenges facing the personalized medicine industry and formulates solutions to foster the development and uptake of personalized medicine. The Working Group provides a unique forum that is composed of the various stakeholders in the industry, resulting in the creation of policy that positively impacts the personalized medicine industry as a whole. With a focus on improving legislative, intellectual property, regulatory, and reimbursement frameworks, the Working Group seeks to better align the incentives connecting the research, development and commercialization of personalized medicine products.

Coalition for Epidemic Preparedness Innovations (CEPI) Working Group

Launched in 2017 in response to the Ebola outbreaks in West Africa, the Coalition for Epidemic Preparedness Innovations (CEPI) is a global public-private partnership focused on accelerating the development of vaccines for emerging infectious diseases (EID). BIO's CEPI Working Group

provides an industry-wide voice on the policy and regulatory issues encountered by CEPI in making progress toward their mission.

Influenza Working Group

The Influenza Working Group addresses the innovation, regulatory, and policy issues impacting both seasonal and pandemic influenza. The Influenza Working Group is inclusive of all products targeted at preventing and treating influenza, including vaccines, antivirals, and diagnostics. Leading BIO's activities around the September 2019 Executive Order on Modernizing Influenza Vaccines, the Influenza Working Group interfaces with senior leaders from the Department of Health and Human Services (HHS), including the Assistant Secretary for Preparedness and Response (ASPR), Food and Drug Administration (FDA), and Centers for Disease Control and Prevention (CDC), and other relevant federal agencies.

COVID-19 Therapeutics Task Force

The COVID-19 Therapeutics Task Force addresses distribution and allocation of therapeutics, R&D funding for new therapeutics, global efforts (ACT Accelerator), communication and education on therapeutics, and recruitment for clinical trials. This group meets regularly. Membership is open to companies working on the development of COVID-19 therapeutics.

COVID-19 Vaccine Task Force

The COVID-19 Vaccines Task Force addresses distribution, access, reimbursement, injury compensation, regulatory, international, and coding issues as related to the development of a COVID-19 vaccine. This group meets bi-weekly and on an ad hoc basis. Membership is open to companies working on the development of a COVID-19 vaccine domestically or internationally.

Finance

Committee on Foreign Investment in the U.S. (CFIUS) Working Group³

The Working Group shares updates and guides advocacy on the implementation of reforms to the Committee on Foreign Investment in the U.S. (CFIUS), which has the authority to review, and potentially alter, foreign investments into the U.S. biotechnology industry. The working group is convened through conference calls on an ad-hoc basis to discuss recent developments in the rulemaking process, exchange insights on the potential impact on the biotechnology industry, and direct BIO's advocacy efforts to shape the rulemaking outcome through comment letters and engagement with the Departments of Commerce and Treasury, as well as Congress. The overarching goal of this working group is to engage in the rulemaking process to avoid an undue impact on the biotechnology sector's ability to enter into global research partnerships as well as attract foreign investments. Working group participants come from a range of backgrounds, principally from C-suite and finance functions, as well as technologists that understand the use and potential applications of emerging biotechnologies.

Finance & Tax Committee³

Concentrates on tax, financial services, securities, and accounting policies that impact member companies and biotech capital formation. This committee advises BIO staff about the impact of legislation and regulations affecting these policy matters and supports BIO's engagement with Treasury, the SEC, and the IRS, as well as Congress and the Administration. Specific financial services areas of interest include the JOBS Act, Sarbanes-Oxley (SOX) Section 404(b), proxy advisory firms, short selling transparency, market structure reform, tick size, accounting and auditing standards, and SEC life science reporting topics. Tax policy emphases include the Orphan Drug Tax Credit, the R&D credit and payroll R&D credit, federal tax treatment of net

operating losses (NOLs), qualified small business stock (QSBS) capital gains treatment, and international tax.

Government Relations

Federal Government Relations Committee¹

Concentrates on educating and lobbying government officials regarding legislative proposals affecting the biotechnology industry. The committee reviews the BIO legislative and regulatory agenda as a whole to set priorities and strategies; initiates BIO policy discussions regarding legislation; and provides advice and recommendations to the Board. Committee members meet with various government officials and their staffs to gain information, offer insight and advice, and buttress BIO positions. The committee collaborates on substance and formulates legislative strategy for major BIO priorities.

Subcommittees:

- IP Task Force
- Orphan Drug Working Group

State Government Relations Committee, Health³

This committee is comprised of BIO member companies and state affiliate organizations and focuses on lobbying state government officials regarding legislative and regulatory healthcare proposals that affect the biotechnology industry. Each member company also designates one representative to serve as their voting member on the committee. Voting members are convened on an ad-hoc basis to set legislative priorities and provide recommendations to the Board of Directors.

International Affairs

International Advocacy Steering Committee¹

Oversees the development of international advocacy strategy and goals, for approval by International Affairs Committee of the Board. Determines priority countries and issues, including biologics regulations, intellectual property rights and market access issues in markets outside of the U.S. Implements the strategy through direct advocacy with foreign governments, U.S. trade and foreign policy officials, and other global stakeholders.

Subcommittees¹

- Brazil/Latin America
- China
- Europe
- India
- Japan
- Korea
- Mexico
- Multilateral Organizations Working Group¹
- South Africa
- Turkey
- Middle East & North Africa (MENA)
- Association of Southeast Asian Nations (ASEAN)
- International Council of Biotech Associations (ICBA)

International Regulatory Committee¹

The International Regulatory Committee works with the Regulatory Affairs Steering Committee to set policy and priorities relating to global regulations of biotechnology products including biotherapeutics and advanced therapies such as cell and gene therapies. The group has a special focus on harmonization of key regulations in priority markets through the International Council on Harmonization (ICH), the Asia Pacific Economic Cooperation (APEC) and the World Health Organization.

Subcommittees

- BIO ICH Experts
- APEC Working Group
- WHO Working Group

Alliance Development

Alliance Development Committee¹

Builds ties with the patient and health advocacy communities in order to create strong, long-term relationships that yield opportunities for patient groups and the biotech industry to collaborate in policy development, advocacy, public awareness and research and product development.

Legal & Intellectual Property

Biopharmaceutical Law Committee¹

Provides additional legal support in the development of BIO analyses and positions on FDA and related product legal/regulatory and legislative issues, as well as issues concerning communications with health care professionals. The committee also helps to identify issues of concern to be proactively addressed by BIO and advises BIO and its other committees as to how particular issues may affect member companies from a legal perspective. The committee is made up of in-house lawyers at BIO's member companies that focus on FDA-related legal, regulatory and legislative issues.

General Counsels Committee¹

Provides a forum for the General Counsels from BIO member-companies to build collegial relationships and exchange information, experiences, and best practices relating to a wide variety of legal and law department issues. Among others, these may include the development and organization of General Counsel offices, corporate governance, securities, antitrust, supervision of outside counsel, and other practice management activities. Participation is open to in-house counsel of member companies.

Intellectual Property Counsels Committee¹

Promotes strong, predictable intellectual property (IP) protection and efficient transfer of IP rights for the biotechnology industry domestically and internationally. This committee is open to in-house patent counsels of BIO member companies. Law firm patent counsels may join only at the designation of a BIO member company. The committee is responsible for developing domestic and international intellectual property policy that benefits the biotechnology industry. The committee reviews and comments on proposed intellectual property legislation and IP-related regulations from federal agencies. The committee will from time to time approve the filing of amicus briefs in cases that impact the biotechnology industry and develop IP-related

position papers, white papers and educational materials. Participation is open to in-house IP counsel of member companies. Focus areas: Amicus, Patent Reform, PTO, and International IP.

Security Committee¹

Shares information relating to security threats and best practices among security officers of BIO member companies. When appropriate, the committee also oversees and monitors security activities relating to BIO events.

Technology Transfer Committee^{1, 2}

The Technology Transfer Committee promotes and facilitates industry/academic research partnerships for the biotechnology community. Committee members include persons directly involved in industry and academia partnerships such as university technology transfer officers, company licensing officers, business development officers, and others. Committee members work to improve business development tools for the industry/university tech transfer community, support BIO's industry intelligence and economic impact analysis of translational research, academic/industry sponsored research best practices, and respond to various state, federal and international legislative matters of vital interest to biotechnology technology transfer partnerships.

Communications

Cost & Value/Communications Committee¹

Helps to direct BIO's Communications Department on the design, implementation and evaluation of public relations, media outreach and consumer awareness efforts under the direction of the Board Standing Committee on Public Awareness. The committee includes senior executives from BIO member companies responsible for public relations, investor relations, public policy, marketing and media relations within their respective companies.

IAMBIO Branding Committee¹

Play an active role in BIO's first-ever banding campaign, IAMBIO. Members of this committee serve as liaisons to their companies to collect video testimonials highlighting the value of biotechnology and the scientists, researchers, and staff that make innovation possible.

Member Services

BIO Business Solutions Advisory Board⁴

Provides strategic direction to BIO's cost-savings program, BIO Business Solutions. Helps in identifying and developing programs and offerings that deliver value to members. Composed of senior executives whose current role and/or industry experience is in finance, sourcing, operations and other related business functions within their respective companies. Participation requires board chair approval. BIO Business Solutions® Advisory Board meets in person annually and has quarterly conference calls.

Eligibility requirements

¹ Participation is limited to a full-time employee of, or in the discretion of BIO an authorized consultant to, R&D intensive ("core") member companies. BIO requires written notice from the R&D intensive member company that the consultant is authorized to act as an official company representative. Further, the consultant must sign a BIO confidentiality agreement indicating that he/she will not share any information learned or obtained through participation on the committee with any client other than the BIO member company which authorized his/her participation on its behalf. A consultant generally may not represent more than one BIO member

company on any single committee, and any requests for information or for BIO to take or modify any policy position shall come directly from the authorizing BIO member company rather than the consultant.

² Participation is open to full-time employees of R&D intensive ("core") member companies and universities only.

³ Participation is open to a full-time employee or representative of all BIO member organizations.

⁴ Participation is by invitation only.

NOTE: Each individual committee also may have additional requirements not listed above. Eligibilities are subject to change.