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 any BIO member company are eligible to join committees. There is no limit to the number of employees a member company can have on a committee.

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 or reach out to the staff contact for any committee of interest.

Healthcare: Science and Regulatory Affairs

Clinical Development Committee[1]

The Clinical Development Committee addresses issues surrounding the conduct, oversight, and analysis of clinical trials in the U.S. and internationally. The Committee proactively identifies issues, develops policy proposals, and provides responses to regulatory and legislative activities regarding clinical trial design, bioresearch monitoring and human subjects protection, and clinical trials registration and results database. This includes, but is not limited to, developing comments and white papers, development of or participation in workshops, and interactions with FDA, as appropriate. In addition to these issues, this Committee will be tasked with certain drug development tools and approaches, including, but not limited to, pre-approval data transparency, utilization of real-world evidence in drug development, and non-proprietary biomarker qualification.

Manufacturing, Quality, and Distribution Committee[1]

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, anticounterfeiting measures and initiatives, and protecting the security and efficacy of the drug and biologics distribution system.

Task Forces:
Innovative Manufacturing Technologies Task Force[1]
Inspections and Compliance Task Force[1]
Supply Chain Task Force[1]

Pediatrics Specialty Committee[1]

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 (BCPA) 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 Taskforce[1]
Innovation in Pediatric Drug Development Taskforce[1]

Post-Market Committee[1]

The Post-Market Committee serves BIO members by identifying issues, developing policy proposals, and responding to regulatory and legislative activities on post-market issues. This includes, but is not limited to, developing comments and white papers, development or participation in workshops, and interactions with FDA, as appropriate. The issue portfolio will continue to include post-market surveillance regulations and drug safety initiatives to advance a 21st century vision of benefit/risk management. It will also include issues related to: utilization of real-world evidence in safety surveillance; post-market study commitments/requirements; communications about therapeutics to patients and physicians; and post-approval data transparency.

Pre-Clinical Safety Committee (BioSafe)[1]

The Pre-Clinical Safety general membership (BioSafe) serves as a resource for BIO members and BIO 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[1]
Pharmacokinetic/Pharmacodynamic Expert Working Group[1]

Rare Disease and Orphan Drugs Specialty Committee[1]

The Rare Disease and Orphan Drugs 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 Health Care Reform and Reimbursement Committee (see description below) and the Regulatory Affairs Committee (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 Group[1]

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.

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, drafts 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 Forces:
Real-World Evidence Task Force[1]
Microbiome Taskforce[1]

Regulatory Review Committee[1]

The Regulatory Review Committee coordinates BIO's review of state, international and federal regulations regarding biomedical innovation. The Committee oversees proactive issue identification, policy development, and responses to regulatory and legislative activities on issues that impact the regulatory decision-making and review of drugs and biologics. 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 also covers issues that impact the timely and effective review of combination products.

Task Force:
Patient-Focused Drug Development Taskforce[1]

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 the Part B Working Group and 340B Working Group.

Subcommittees:
Transformative Therapies Working Group[1]
The Transformative Therapies Working Group meets on an ad hoc basis and develops solutions to ensure patient access to cellular and gene therapies, such as CAR-T.

Medicare Part B Working Group[1]
The Part B Work Group meets on an ad hoc basis to discuss reimbursement policies affecting Medicare Part B.

State Policy, Access and Reimbursement Committee[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.

Subcommittee:
340B Working Group[1]
The group discusses policy around the 340B program i.e. duplicate discounts, contract pharmacies, etc.

Healthcare: Specialty Markets

Antimicrobial Resistance (AMR) Working Group[1]

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.

Biodefense Policy Working Group[1]

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.

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.

Personalized Medicine & Diagnostics (PMDx) Working Group[1]

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.

Vaccines Regulatory Affairs Committee[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.

Vaccines Policy Working Group[1]

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 State Working Group

The Vaccines State Working Group addresses vaccine policy issues at the state level, including vaccine research and innovation, financing, and vaccine confidence. As necessary, subgroups focused on specific states or issues are formed.

Government Relations

Federal Government Relations Committee[1]

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.

Subcommittee:

IP Task Force[1]
The purpose of the group is to share intel and strategize on federal IP legislation.

Orphan Drug Tax Credit Working Group[1]
The purpose of the group is the share up-to-the-minute tax updates regarding the orphan drug tax credit.

Tax Working Group[1]
The purpose of the group is the share up-to-the-minute tax updates.

State Government Relations Committee, Health[3]

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 Committee[1]

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.

Subcommittees:

Association of Southeastern Asian Nations (ASEAN) Working Group[1]

This working group welcomes representation from member companies interested in policy and business development in the ASEAN economies, including Thailand and Malaysia. The group is also responsible for developing regional advocacy strategy and goals, for approval by International Affairs Committee of the Board. Tasks include determining priority countries and issues, including biologics regulations, intellectual property rights and market access issues, and advise ASEAN-related programming at relevant BIO events. Group also provides input on implements the strategy, which can include direct advocacy with foreign governments, U.S. trade and foreign policy officials, and other global stakeholders.

Brazil/Latin America Working Group[1]

BIO's multidisciplinary advocacy program in Latin America addresses the legal, regulatory, and market access issues that ensure a healthy policy environment supportive of the business interests of our members, small and large, and that will likewise support the growth of a dynamic local innovative ecosystem. This multidisciplinary, win-win approach to advocacy in Latin America is particularly important given the region's leadership in agricultural and industrial biotech and aspirations to further integrate itself in the global biopharma space - accordingly, this Working Group will address biotech matters holistically and across all biotech sectors represented in BIO's broad membership.

China Working Group[1]

Oversees the development of advocacy strategies and goals pertaining to the China market. Determines priority issues and key messaging in the execution of relevant BIO strategies and initiatives in China, and engages in direct advocacy with relevant stakeholders, U.S. trade and foreign policy officials.

India Working Group[1]

This working group oversees BIO's strategic activities in India and aims to ensure BIO's positions on IP, reimbursement, regulatory and investment are communicated to government officials both in the US and India through direct advocacy.

Japan Working Group[1]

Oversees the development of advocacy and international-relation efforts pertaining to the Japan market. Determines priority issues and key messaging in the execution of relevant BIO initiatives and engages in direct advocacy with stakeholders and U.S. trade and foreign policy officials.

Middle East and North Africa Working Group[1]

This working group provides input into BIO's advocacy efforts in the Middle East and North Africa region. With a focus on advancing policies that foster biotechnology innovation and assisting in ensuring market access, this working group supports BIO's efforts to build a program around the BIO International Convention for officials.

Multilateral Organizations Working Group[1]

This working group shapes BIO's strategy and positions with regards to a range of workstreams at multilateral institutions, such as WHO, OECD and other UN institutions. With a strong focus on biopharmaceutical workstreams, the goal of BIO's work in this space is to minimize harmful workstreams at multilateral institutions, while supporting more positive, collaborative workstreams.

South Africa Working Group[1]

BIO continues to increase its engagement in the South African market by supporting local partners with the growth of a domestic industry and advancing positive national legislation. This working group shapes BIO's program in South Africa, including the recruitment of officials to the annual BIO International Convention.

Turkey Working Group[1]
BIO continues to place emphasis on easing market access restrictions in the Turkish market. This working group shapes BIO's advocacy work in Turkey, including the program for Turkish officials at the annual BIO International Convention.

International Regulatory Committee[1]

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.

Subcommittee:
ICH Working Group[1]
The International Council on Harmonization (ICH) working group is a working group under the International Regulatory Committee. The working group focuses on strategies and priorities for harmonization of regulatory guidelines through the International Council on Harmonization (ICH).

Alliance Development

Alliance Development Committee[1]

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 Committee[1]

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 Committee[1]

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 Committee[1]

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 Committee[1]

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.

Finance

Committee on Foreign Investment in the U.S. (CFIUS) Working Group[3]

BIO maintains a staff-level working group to share updates and guide 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 Committee[3]

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.

Communications

Agriculture & Environment Communications Advisory Group[1]

The Agriculture & Environment Communications Advisory Group represents member companies within BIO's Food & Ag and Industrial & Environmental Sections and provides strategic guidance to BIO staff regarding:

- Implementing BIO's rebranding strategy for communicating about the bio-based innovations that bolster the bio-economy and improve plant, animal, human and environmental health;
- Leveraging the work being done on gene editing via the BIO/ASTA Innovature initiative as part of our overall strategy;
- Developing and disseminating information and materials in support of BIO's policy positions and advocacy priorities;
- Engaging stakeholder allies and third-party influencers; and
- Monitoring media coverage, media trends and engaging in rapid response when appropriate.

Cost & Value/Communications Committee[1]

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.

Innovature (Genome Editing) Communications Working Group[3]

The Innovature Communications Working Group provides member-driven strategic guidance to BIO and allied partners on executing the work under the communications pillar of the Innovature initiative. The aim of Innovature is to raise awareness and drive consumer acceptance of innovation in food and agriculture, with the current focus on the benefits of gene editing technology. The Communications Working Group is open to the designated company representatives within BIO's Food and Agriculture Section and BIO's Industrial & Environmental Section, plus members of the American Seed Trade Association (ASTA) and other associations, as appropriate.

Member Services

BIO Business Solutions Advisory Board[4]

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.