BIO Staff-Level Policy Committees

Joining a BIO committee is the best way to inform our domestic and international agendas, participate in public outreach, advocacy activities, and stay informed. Committee participation is open to all employees of BIO member companies. Members participate in committee meetings 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, external affairs, tax, investment, communications, and legal expertise, and connections to industry influencers and stakeholders;
- Ability to help shape BIO's domestic and international policy agenda; and
- Timely updates and newsletters on issues of importance to their companies.

WHO CAN JOIN?

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.

HOW IT WORKS

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 recurring basis with occasional in-person meetings, as needed or appropriate. Attendance is not mandatory.

Meeting cadence is subject to change. Please reach out to **biomember@bio.org** for meeting cadence of subcommittees and task forces.

COMMUNICATIONS

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

Ready to join? Have questions?

Contact **biomember@bio.org** with questions or to request to join a committee.
Not yet a member? Visit **bio.org/join** and complete an online membership application today.

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REGULATORY AFFAIRS STEERING COMMITTEE (RASC)[1]

Monthly

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 biopharmaceutical companies to research and develop new therapeutics, 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.

FDA IND EFFICIENCY[1]

Monthly

The FDA IND Efficiency Task Force focuses on opportunities to modernize and streamline early-stage drug development in the U.S., with an emphasis on IND requirements and review processes. This group aims to identify and advance policy solutions that support a more efficient, risk-based, and predictable pathway for investigational products.

BIOMARKERS[1]

Monthly

The Biomarkers Task Force advocates for policies and best practices that accelerate the development, qualification, and implementation of biomarkers across the product lifecycle. The task force works closely with our BIO members and key stakeholders to address scientific, regulatory, and operational challenges, while developing recommendations to strengthen frameworks that enable biomarker-driven innovation. It also serves as a forum to keep members informed of emerging biomarker science, policy developments, and advocacy activities, fostering alignment on priority issues and strategic actions.

REGENERATIVE MEDICINE (CGT) COMMITTEE[1]

Monthly

The Regenerative Medicine (CGT) Committee aims to advance regulatory science and policy supporting the development of innovative cell and gene therapies (CGT). The committee addresses emerging FDA initiatives and scientific, regulatory, clinical, nonclinical, and manufacturing challenges unique to CGTs, while advocating for greater regulatory predictability and the use of innovative development approaches across the product lifecycle. These priorities help share BIO policy positions, FDA comments, scientific and regulatory perspectives, and opportunities for BIO-FDA scientific and regulatory exchanges.

Task Forces:

- Cell & Gene Therapy Nonclinical

BIOSAFE (NONCLINICAL) COMMITTEE[1]

Quarterly

The BioSafe General Membership 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 nonclinical 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 nonclinical safety of biologics.

Task Forces:

- BioSafe Annual Meeting Planning Group
- Off-Target Safety Assessment

MANUFACTURING, QUALITY, AND DISTRIBUTION COMMITTEE[1]

Every two months

The Manufacturing, Quality, and Distribution Committee proactively identifies issues, develops policy proposals, and provides responses to regulatory and legislative activities regarding biotechnology manufacturing, including international harmonization of manufacturing requirements. This includes, but is not limited to, developing comments and white papers, development of or participation in workshops, and interactions with FDA, as appropriate.

Task Forces:

- Advanced Manufacturing & Innovative Technologies
- Inspections
- Predictive Stability

RARE DISEASE AND ORPHAN DRUG (RDOD) COMMITTEE[1]

Monthly

The RDOD Committee focuses on rare disease therapeutic development, regulatory affairs, and clinical approaches to advance regulatory science and policy approaches that help bring novel therapies to patients with rare diseases. The committee addresses emerging FDA initiatives and the unique scientific and regulatory challenges associated with rare diseases, while advocating for greater regulatory consistency, acceptance of fit-for-purpose evidence generation and innovative patient-focused approaches. These priorities help shape BIO policy positions, FDA comments and opportunities for BIO-FDA scientific and regulatory exchanges.

ARTIFICAL INTELLIGENCE COMMITTEE[1]

Monthly

The Artifical Intelligence Committee focuses on issues related to the use of artificial intelligence and machine learning (AI/ML) in drug development. The group aims to advance policy positions to shape clearn, science-based frameworks for the use of AI/ML in regulatory submissions, and provides a forum to track, discuss, and respond to AI/ML-related regulatory developments.

INTERNATIONAL REGULATORY COMMITTEE[1]

Every two months

The International Regulatory Committee (IRC), in coordination with the Regulatory Affairs Steering Committee (RASC) and other BIO SciReg committees, sets BIO's strategic priorities for international regulatory policy relating to biotechnology product development and innovation across the full range of modalitites and regulatory processes. IRC's core focus is harmonization of key regulations in priority markets, anchored by continuous engagement with the International Council for Harmonisation (ICH) and re-established engagement with the Asia-Pacific Economic Cooperation (APEC) Regulatory Harmonization Steering Committee (RHSC). IRC also maintains a broader, evolving mandate to advance additional international regulatory priorities, including FDA's global role, regulatory reliance, and bilateral/multilateral engagement, as determined through ongoing committee discussion.

Task Forces:

- ICH Q5E Support Group

CLINICAL TRIALS COMMITTEE[1]

Monthly

The Clinical Trials Committee aims to identify and advance policy solutions that improve the efficiency of clinical trial initiation and execution in the U.S. The Committee works with HHS, FDA, national organizations, and other stakeholders to address shared operational and policy challenges affecting the conduct of clinical research.

Healthcare: Policy and Research

POLICY, ACCESS AND REIMBURSEMENT COMMITTEE (PARC)[2]

Weekly, Thursday, 3:00-4:00 pm ET

The Policy, Access and Reimbursement Committee (PARC) focuses on federal legislative and regulatory proposals regarding access and reimbursement to 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. This committee develops positions to maintain and expand market-based delivery systems to ensure patient access to biotechnology therapies, such as by combating policies like Most Favored Nation (MFN) drug pricing. Members of the committee review health reform and reimbursement issues from a variety of perspectives including legislative, regulatory, and economic. Issues include PBM reform, prior authorization/step therapy, and broader patient affordability policies. Members of the committee meet routinely with government officials regarding legislation and agency regulations.

STATE POLICY, ACCESS AND REIMBURSEMENT COMMITTEE (STATE PARC)[2]

Biweekly, Tuesday, 3:00-4:00 pm ET

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.

340B/IRA TECHNICAL IMPLEMENTATION COMMITTEE[2]

Weekly, Friday, 12:00-1:00 pm ET

The 340B/Inflation Reduction Act (IRA) Technical Implementation Workgroup focuses on both state and federal efforts to increase transparency and program integrity within the 340B Program. The workgroup also engages with regulators on issues related to duplicate discounts between the IRA and the 340B Program and technical requirements for manufacturers to provide access to the Maximum Fair Price (MFP) under the IRA. Members of the workgroup review 340B and IRA implementation issues through policy, legal, government pricing, and compliance perspectives. Members respond to legislation and regulatory guidance and advocate for reforms by submitting comments and engaging directly with state legislators and regulators.

SMALL BIOTECH WORKING GROUP[2]

Ad Hoc

This working group focuses on policy issues that impact small biotech companies, including the small biotech provisions included in the Inflation Reduction Act (IRA). This group brings issues to CMS as well as the Hill to advocate for a policy apparatus that considers and understands smaller companies' unique circumstances.

DATA PRIVACY COMMITTEE[2]

Ad Hoc

The Data Privacy Committee is a resource for BIO members and BIO staff to explore issues relating to data privacy and AI. The group aims to develop policy positions that promote the safe, secure, and responsible use of artificial intelligence and data sharing technologies throughout the commercialization process to deliver medicines to patients.

VACCINES POLICY COMMITTEE[1]

Biweekly, Tuesday, 3:00-4:00 pm ET

The Vaccines Policy Committee 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.

BIODEFENSE POLICY COMMITTEE[1]

Biweekly, Wednesday, 3:00-4:00 pm ET

The Biodefense Policy Committee 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]

Monthly, 3rd Thursday, 1:00-2:00 pm ET

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.

Task Forces and Subcommittees:

- Influenza
- Global Health

ANTIMICROBIAL RESISTANCE (AMR) COMMITTEE[1]

Biweekly, Wednesday, 11:00 am - 12:00 pm ET

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

(AMR), and incentives for both antimicrobial and vaccine development.

Finance

FINANCE & TAX COMMITTEE[3]

Bimonthly

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 COMMITTEE[1]

Weekly, Monday, 2:00-3:00 pm ET

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.

STATE GOVERNMENT RELATIONS COMMITTEE, HEALTH[3]

Monthly, 3rd Wednesday, 2:00-3:00 pm ET

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

NATIONAL SECURITY AND INTERNATIONAL AFFAIRS STEERING COMMITTEE[1]

Monthly

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.

Alliance Development

ALLIANCE DEVELOPMENT COMMITTEE[1]

Monthly, 3rd Thursday, 2:00-3:00 pm ET

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

BIO GENERAL COUNSELS STEERING COMMITTEE (GCC)[1]

Monthly, 4th Wednesday, 2:00-3:00 pm ET

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 the General Counsel or Chief Legal Officer, with a limit of one committee member per company.

INTELLECTUAL PROPERTY COUNSELS' COMMITTEE[1]

Monthly, 2nd Tuesday, 12:00-1:00 pm ET

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.

Subcommittee:

- IP Task Force

BIO INDUSTRY-ACADEMIC NETWORK[2]

Quarterly

The BIO Industry-Academic Network 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

COMMUNICATIONS WORKING GROUP[1]

Quarterly

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 is limited to senior executives from BIO member companies responsible for public relations, investor relations, public policy, marketing and media relations within their respective companies.

VACCINES COMMUNICATIONS WORKING GROUP[1]

Monthly

Information sharing and strategy coordination across the senior communicators responsible for vaccines at BIO member companies. This working group will address broad policy topics that impact public health, reimbursement and sentiment related to vaccines.

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