Health

Antimicrobial Resistance (AMR) Working Group
Staff Contact: Gregory Frank (gfrank@bio.org)
Schedule: Every other Wednesday, 1:00 PM
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
Staff Contact: Phyllis Arthur (parthur@bio.org)
Schedule: Every other Wednesday, 3:00 PM
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.

Health Care Reform & Reimbursement Committee
Staff Contact: Laurel Todd (ltodd@bio.org)
Schedule: Every Tuesday, 3:00 PM
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.

State Health Care Reform & Reimbursement Committee
Staff Contact: Arielle Gurwitch (agurwitch@bio.org)
Schedule: Every other Wednesday, 3:00 PM
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.

Personalized Medicine & Diagnostics (PMDx) Working Group
Staff Contact: Phi Vu (pvu@bio.org)
Schedule: Every second Thursday of the month, 2:00 PM
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,

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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.

**Regulatory Affairs Committee**

Staff Contact: Cartier Esham (cesham@bio.org)
Schedule: Every second Wednesday of each month, 2:00 PM
Acts as a Steering Committee for all staff-level Science & Regulatory Committees and Working Groups. The RAC takes the lead or makes assignments to Committees and Working Groups on implementation of user fee agreements, including continuous engagement activities with FDA. The RAC 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 RAC responds to proposed regulations and draft guidance documents as necessary and holds liaison meetings with FDA to identify and discuss regulatory best practices.

**Subcommittees:**
- Pre-Clinical (BioSafe) Committee
- Clinical Development Committee
- Regulatory Review Committee
- Post-Market Committee
- Manufacturing, Quality and Distribution Committee
- Pediatrics (Specialty) Committee
- Rare Disease & Orphan Drugs (Specialty) Committee
- Combination Products Working Group
- Biosimilars & BsUFA (Science & Regulatory) Working Group
- PDUFA Working Group

**Vaccines Policy Working Group**

Staff Contact: Phyllis Arthur (parthur@bio.org)
Schedule: Every other Tuesday, 4:00 PM
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.

**Subcommittees:**
- Vaccines Policy State Task Force

**Vaccines Regulatory Affairs Committee**

Staff Contact: Phyllis Arthur (parthur@bio.org)
Schedule: Every fourth Thursday, 1:00 PM
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.
**Government Relations**

**Government Relations Committee**
Staff Contact: Jeanne Haggerty (jhaggerty@bio.org)
Schedule: Every Monday when Congress is in session, 2:00 PM
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:**
- Government Relations Committee
- Tax Subcommittee
- Government Relations Committee, Rare Disease & Orphan Drug Working Group
- Executive Government Relations Committee

**Biosimilars Implementation Committee**
Staff Contact: Jeanne Haggerty (jhaggerty@bio.org)
Schedule: First Thursday of every month, 4:00 PM
Serves as the focal point for information sharing and the coordination of all BIO activity related to the implementation of the Biologics Price Competition and Innovation (BPCI) Act. Proactively identifies key developments and refers them to the appropriate policy development and advocacy committees within BIO to be addressed.

**State Government Relations Committee, Health**
Staff Contact: Patrick Plues (pplues@bio.org)
Schedule: First and third Wednesday of the month at 2:00 PM from January – June; first Wednesday of the month from July – December
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**
Staff Contact: Joseph Damond (jdamond@bio.org)
Schedule: As needed, subcommittees meet as needed
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:**
- China Working Group
- India Working Group
- Brazil/Latin America Working Group
- International Biologics Regulation Working Group
- Global IP Rights Working Group
- U.S. Trade Policy Working Group
- Middle East and North Africa Working Group
- Turkey Working Group, South Africa Working Group
- APEC Working Group

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Alliance Development

Alliance Development Committee
Staff Contact: Cara Toman (ctoman@bio.org)
Schedule: Every second Thursday of each month
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
Staff Contact: John Murphy (jmurphy@bio.org)
Schedule: Every third Wednesday of each month, 3:00 PM; subcommittees meet as needed
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.

Subcommittees:  
Sunshine & Transparency WG
Product Communications WG
OIG Working Group WG

General Counsels Committee
Staff Contact: Peter McHugh (pmchugh@bio.org)
Schedule: Meets in-person three times per year: once in the Spring (West Coast), once in the Fall (East Coast), and once at the Convention (location TBD each year); subcommittee meets as needed
Provides a forum for BIO member-company General Counsels to build collegial relationships and exchange information, experiences, and best practices relating to a wide variety of legal and law department issues, including the development and organization of General Counsel offices, and issues relating to corporate governance, securities, antitrust, supervision of outside counsel, and other practice management activities. Committee participation also keeps members up-to-date on the myriad legislative, regulatory, and international issues impacting the biotechnology industry, through – among other avenues – participation on relevant subcommittees, and in-person committee meetings several times a year.

Subcommittee:  Amicus Subcommittee

Intellectual Property Counsels Committee
Staff Contact: Hans Sauer (hsauer@bio.org)
Schedule: Meets in-person twice per year, teleconferences as needed; subcommittees as needed
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. Focus areas: Amicus, Patent Reform, PTO, and International IP

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Security Committee
Staff Contact: Pat Fogarty (pfogarty@bio.org)
Schedule: Meets two times annually: Exact dates and times vary (one pre-Convention meeting & one post-Convention meeting).
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
Staff Contact: Pete Pellerito (ppellerito@bio.org) and Austin Donohue (adonohue@bio.org)
Schedule: As needed
The Technology Transfer Committee promotes and facilitates industry/university 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, identify best practices, and respond to various legislative, federal, state, and international initiatives that might impact university/industry collaborations.

Finance

Finance & Tax Committee
Staff Contact: Charles Crain (ccrain@bio.org)
Schedule: Every first Thursday of each month, 2:00 PM
Concentrates on financial services, securities, accounting, tax, and other policy areas regarding capital formation that impact member companies. This committee advises BIO staff about legislation and regulations affecting these policy matters. Specific financial services areas of interest include the JOBS Act, market structure reform, Sarbanes-Oxley, SEC Regulations D and A, revenue recognition, accounting and auditing standards, and SEC life science reporting topics. Tax policy emphases include the Therapeutic Discovery Project, improvements to the R&D tax credit, federal tax treatment of Net Operating Losses (NOLs), and international tax proposals such as a territorial tax system.

Communications

Cost & Value/Communications Committee
Staff Contact: Ken Lisaius (klisaius@bio.org)
Schedule: Quarterly at 2:00 PM; subcommittees meet as needed
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.

Subcommittees:
- Food & Agriculture Advisory Group
- Industrial & Environmental Advisory Group

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Member Services

BIO Business Solutions Advisory Board
Staff Contact: Kelly Martin (kmartin@bio.org)
Schedule: Board meets once through in-person meetings and twice via conference calls in a year
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.

Food & Agriculture

Plant Policy Committee
Staff Contact: Clint Nesbitt (cnesbitt@bio.org)
The Committee is responsible for strategic planning and work plan objectives, oversight of work plan implementation, and policy position recommendations on commodity agriculture issues. Membership is composed of companies that produce commodity agriculture products for direct human and animal use, i.e., corn, soybeans, sugar, cotton and vegetables.

Task Forces:
China Task Force
Staff Contact: Matt O’Mara (momara@bio.org)
The China Task Force is charged with implementing BIO’s work plan related to U.S.-China trade relations with respect to agricultural biotechnology and coordinating with members of the U.S. agricultural value chain and global partners.

US-EU TTIP Task Force
Staff Contact: Matt O’Mara (momara@bio.org)
The TTIP Task Force is responsible for developing BIO’s position on the US-EU Trans-Atlantic Trade and Investment Partnership (TTIP) and coordinating with members of the U.S. agricultural value chain and industry partners in the European Union.

Animal Biotechnology Policy Committee
Staff Contact: Adrianne Massey (amassey@bio.org)
The Committee is responsible for strategic planning and work plan objectives, oversight of work plan implementation, and policy position recommendations on animal-based produced product issues. Membership is composed of companies that enhance livestock production through animal genomics, animal cloning and transgenics. Other areas would include development of diagnostics, vaccines and animal-made pharmaceuticals to improve animal and human health.

Science and Regulatory Working Group (SRWG)
Staff Contact: Clint Nesbitt (cnesbitt@bio.org)
The SRWG analyzes and responds to emergent and evolving regulatory policies related to plant agricultural biotechnology; promotes development of appropriate, science-based regulatory policy in the United States; serves as a resource on scientific issues; and provides a forum for stakeholders to discuss issues and concerns regarding plant agricultural biotechnology.

Food and Agriculture Communications Advisory Group
Staff Contact: Karen Batra (kbatra@bio.org)
The Food & Agriculture Communications Advisory Group serves the interests of BIO’s Food & Ag Section by providing strategic guidance to BIO staff and policy committees regarding:

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- Messaging on topics, including general benefits, priority issues and key concepts of particular relevance to BIO Food & Ag Section members;
- Development and dissemination of information and materials in support of BIO’s positions and advocacy priorities;
- Implementation of proactive communications tactics in support of BIO’s positions and advocacy priorities;
- Issues management and reactive communications; and
- An identification and engagement strategy with third-party allies and influencers.

**Food and Agriculture Federal Government Relations Committee**
Staff Contact: Dana O’Brien (dobrien@bio.org)
The Federal Government Relations Committee oversees BIO’s Legislative and Executive Branch activities on all issues related to agricultural biotechnology. BIO maintains relationships with national biotechnology and agribusiness organizations, and works to build and maintain relationships with policy makers in Congress and at Federal Agencies.

**Food and Agriculture State Government Relations Committee**
Staff Contact: Gene Harrington (gharrington@bio.org)
The State Government Relations Committee oversees BIO’s sub-national policy management activities on all issues related to agricultural biotechnology. BIO maintains relationships with state and regional biotechnology and agribusiness organizations, and retains contract lobbyists in 15 states under the guidance of the committee.

**Food and Agriculture Law Committee**
Staff Contact: Don Atkins (datkins@bio.org)
The Law Committee implements a legal strategy approved by the FASGB, which helps to defend and advance the interests of the agricultural biotechnology industry. The Committee also provides support on legal issues of interest to the Food and Agriculture Section.

**Industrial & Environmental**

**Federal Government Relations Committee**
Staff Contact: Erick Lutt (elutt@bio.org)
For lobbyists and those involved in government affairs for industrial biotechnology products and processes.

**State Government Relations Committee**
Staff Contact: Stephanie Batchelor (sbatchelor@bio.org)
For lobbyists and those involved in state government affairs for industrial biotechnology products and processes.

**Communications Committee**
Staff Contact: Paul Winters (pwinters@bio.org)
For those involved in all aspects of press and communications work dealing with industrial biotechnology.

**Regulatory Affairs Committee**
Staff Contact: Clare Thorp (cthorp@bio.org)
To address the implementation of several regulations which will impact our members. The Committee’s current top three policy issues are: Toxic Substances Control Act (TSCA), the new bioengineered food disclosure legislation and regulations, and the EPA regulations affecting algae production systems.

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Renewable Specialty (Flavors, Food Ingredients, Fragrances) Chemicals Working Group

Staff Contact: Rina Singh (rsingh@bio.org)
Improve acceptance of and enhance the use of biotechnology and bio-based processes in pharmaceutical intermediates, fine chemicals, food additives, flavors, fragrances, personal care and nanotechnology.

Biobased Products Working Group

Staff Contact: Rina Singh (rsingh@bio.org)
Deals with developing policy initiatives to advance the biobased products industry.

Biofuels Working Group

Staff Contact: Erick Lutt (elutt@bio.org)
Deals with developing policy initiatives to advance the biofuels industry.

Climate, Sustainability, and Feedstocks Working Group

Staff Contact: Stephanie Batchelor (sbatchelor@bio.org)
Guides engagement with industry sustainability certification efforts and development of policy options for climate legislation to enhance the uptake of all forms of industrial biotechnology.

Synthetic Biology Working Group

Staff Contact: Rina Singh (rsingh@bio.org)
The Synthetic Biology working group develops and implements strategies to highlight the significant contributions of Synthetic Biology to the industry and society. Current priorities are to:
1) Monitor and participate in public policy decisions affecting synthetic biology and 2) Enhance communication with, and educate, policy makers and the public to ensure the continued growth and success of the industry.

Sustainable Supply Chain Task Force

Staff Contact: Stephanie Batchelor (sbatchelor@bio.org)
To address the sustainable feedstock supply chain and lack of consensus on which North American feedstocks are perceived as acceptable by consumer packaged goods companies and retailers for use in the production of bioplastics and biochemicals. This task force reports to the Climate, Sustainability, and Feedstocks Working Group.

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.