BIO Staff-Level Policy Committees

November 2018

Health

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

Personalized Medicine & Diagnostics (PMDx) Working Group[1]
Staff Contact: Phi Vu (pvu@bio.org)
Schedule: Every second Thursday of the month, 2:00 PM
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.

Policy, Access and Reimbursement Committee (PARC)[1]
Staff Contact: Mallory O'Connor (moconnor@bio.org)
Schedule: Every Tuesday, 3:00 PM
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.

Subcommittee:
Transformative Therapies Working Group[1]

State Policy, Access and Reimbursement Committee (State PARC)[1]
Staff Contact: Jack Geisser (jgeisser@bio.org)
Schedule: Every other Wednesday, 3:00 PM
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.

Regulatory Affairs Steering Committee (RASC)[1]
Staff Contact: Cartier Esham (cesham@bio.org)
Schedule: Every second Wednesday of each month, 2:00 PM
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.

Subcommittees:
Pre-Clinical Safety Committee (BioSafe)[1]
Clinical Development Committee[1]
Regulatory Review Committee[1]
Post-Market Committee[1]
Manufacturing, Quality and Distribution Committee[1]
Pediatrics Committee[1]
Rare Disease & Orphan Drugs Committee[1]
Regenerative Medicine Working Group[1]
Microbiome Task Force[1]
Patient-Focused Drug Development Taskforce[1]
Real-World Evidence Taskforce[1]

Vaccines Policy Working Group[1]
Staff Contact: Phyllis Arthur (parthur@bio.org)
Schedule: Every other Tuesday, 4:00 PM
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.

Subcommittee:
State Vaccines Policy Task Force[1]

Vaccines Regulatory Affairs Committee[1]
Staff Contact: Greg Frank (gfrank@bio.org)
Schedule: Every fourth Thursday, 1:00 PM
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.

Government Relations

Government Relations Committee[1]
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[1]
Government Relations Committee, Rare Disease & Orphan Drug Working Group[1]
Executive Government Relations Committee[1]

State Government Relations Committee, Health[3]
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[1]
Staff Contact: Joseph Damond (jdamond@bio.org), Debbie Johnson (djohnson@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:
Multilateral Organizations Working Group[1]
Global Regulatory Harmonization Working[1]
WHO Working Group[1]
India Working Group[1]
Brazil/Latin America Working Group[1]
China Working Group[1]
ASEAN Working Group[1]
Japan Working Group[1]

China Agriculture Task Force[1]
Europe Agriculture Task Force[1]
South Africa Working Group[1]
Middle East and North Africa Working Group[1]
Turkey Working Group[1]

Alliance Development

Alliance Development Committee[1]
Staff Contact: Mary Bordoni (mbordoni@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.

Subcommittee: Alliance Development State Working Group[1]

Legal & Intellectual Property

Biopharmaceutical Law Committee[1]
Staff Contact: John Murphy (jmurphy@bio.org)
Schedule: Meets via teleconference as needed; 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:
Product Communications WG[1]
OIG Working Group WG[1]

General Counsels Committee[1]
Staff Contact: Peter McHugh (pmchugh@bio.org)
Schedule: Meets in-person twice per year: once in the Spring (East Coast) and once in the Fall (West Coast); subcommittee meets as needed
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. Committee participation keeps BIO members up-to-date on a myriad of legislative, regulatory, and international issues that impact the biotechnology industry. The GCC only meets twice per year (spring and fall) and complements other avenues of participation at BIO – i.e. participation on relevant committees and subcommittees.

Subcommittee: Amicus Subcommittee[1]

Intellectual Property Counsels Committee[1]
Staff Contact: Hans Sauer (hsauer@bio.org) and Melissa Brand (mbrand@bio.org)
Schedule: Meets in-person twice per year, teleconferences held monthly; 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[4], Patent Reform, PTO, and International IP

Security Committee[1]
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[1 2]
Staff Contact: Pete Pellerito (ppellerito@bio.org) and Austin Donohue (adonohue@bio.org)
Schedule: As needed
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

Finance & Tax Committee[3]
Staff Contact: Cameron Arterton (carterton@bio.org)
Schedule: First Thursday of each month, 2:00 PM (Eastern)
Concentrates on tax, financial services, securities, and accounting policies that impact member companies and biotech capital formation. This committee advises BIO staff about 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

Cost & Value/Communications Committee[1]
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[1]
Industrial & Environmental Advisory Group[1]

Member Services

BIO Business Solutions Advisory Board[4]
Staff Contact: Kelly Martin (kmartin@bio.org)
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.

Food & Agriculture

Innovation Strategy Council
Staff Contact: Dan Jenkins (djenkins@bio.org)
The Innovation Strategy Council is responsible for ensuring BIO executes a coordinated, deliberate, future-looking, and pro-innovation strategy in support of biology-based food, agricultural, health, and environmental solutions and systems. The Council, because of its holistic approach around these innovation themes, looks across regulatory, acceptance and alliance development, government affairs, communications, industry, and corporate affairs. It also keeps an eye on both domestic and international matters. It serves as the primary body to provide recommendations to the Board. BIO staff may call together subsets of the Council (or the full group, if appropriate) to obtain strategic guidance, short of Board approval, on key challenges when they arise. The Council also may establish and dismantle Special Committees and Exploratory Groups, as appropriate, to cover or investigate BIO's role on emerging key issues for industry.

Science & Regulatory Teams[1]
Staff Contact: Clint Nesbitt (cnesbitt@bio.org)
Managed by the Senior Director of Science and Regulatory Affairs who is responsible for coordinating regulatory strategy for the Food & Agriculture Section. Teams will regularly meet individually and will meet occasionally, as a committee of the whole, to develop and oversee the execution of regulatory policy goals and objectives that promote the research, development, and commercialization of biology-based food, agricultural, health, and environmental solutions and systems. Committee of the whole meetings will enable BIO members to analyze and respond to, as a broad group engaged in regulatory affairs, emergent and evolving science and regulatory matters and provide recommendations, as necessary, to the Innovation Strategy Council, any other Committees, and the Board. Two current teams are set forth below:

Plant Regulatory Team[1]
Staff Contact: Clint Nesbitt (cnesbitt@bio.org)
The Plant Regulatory Team is focused on establishing an improved regulatory paradigm for biotechnology-derived plants, including both transgenic and gene edited. The committee leads the development of science-based regulatory policy strategies to drive risk proportionate regulation for these applications for the betterment of industry and consumers.

Animal Regulatory Team[1]
Staff Contact: Clint Nesbitt (cnesbitt@bio.org)
The Animal Regulatory Team is focused on establishing an improved regulatory paradigm for biotechnology-derived animals, including both transgenic and gene edited. The committee leads the development of science-based regulatory policy strategies to drive risk proportionate regulation for these applications for the betterment of industry and consumers.

Market Access Teams[1]
Staff Contact: Sarah Gallo (sgallo@bio.org)
Managed by the Director of Market Access who is responsible for coordinating stakeholder engagement and acceptance strategies for the Food & Agriculture Section. Teams will regularly meet individually and will meet occasionally, as a committee of the whole, to develop and oversee the execution of goals and objectives that promote the acceptance of and active support for biology-based food, agricultural, health, and environmental solutions and systems. Committee of the whole meetings will enable BIO members to analyze and respond to, as a broad group engaged in regulatory affairs, emergent and evolving science and regulatory matters and provide recommendations, as necessary, to the Innovation Strategy Council, any other Committees, and the Board. More information about specific teams will be forthcoming.

Genome Editing Advisory Group[3]
Staff Contact: Dan Jenkins (djenkins@bio.org)
The Genome Editing Advisory Group provides member-driven strategic guidance to BIO and allied partners to drive consumer acceptance of genome editing technology for food, agriculture, and the environmental products and systems – including strategic communications and stakeholder engagement efforts. The advisory group is open to members of the Food and Agriculture Section Governing Board and the Industrial & Environmental Section Governing Board or their senior staff designees, plus executive members of the American Seed Trade Association (ASTA) and other associations, as appropriate.

Food and Agriculture Communications Advisory Group[1]
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:

- 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[1]
Staff Contact: Kyle Kunkler (kkunkler@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[3]
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[1]
Staff Contact: Kristin Landis (klandis@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[1]
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[3]
Staff Contact: Stephanie Batchelor (sbatchelor@bio.org)
For lobbyists and those involved in state government affairs for industrial biotechnology products and processes.

Communications Committee[1]
Staff Contact: Connor McKoy (cmckoy@bio.org)
For those involved in all aspects of press and communications work dealing with industrial biotechnology.

Regulatory Affairs Committee[1]
Staff Contact: Kate Shenk (kshenk@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.

Renewable Specialty (Flavors, Food Ingredients, Fragrances) Chemicals Working Group[1]
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[1]
Staff Contact: Rina Singh (rsingh@bio.org)
Deals with developing policy initiatives to advance the biobased products industry.

Biofuels Working Group[1]
Staff Contact: Erick Lutt (elutt@bio.org)
Deals with developing policy initiatives to advance the biofuels industry.

Climate, Sustainability, and Feedstocks Working Group[1]
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/Gene Editing Working Group[1]
Staff Contact: Rina Singh (rsingh@bio.org)
The Synthetic Biology and Gene Editing working group develops and implements strategies to highlight the significant contributions of Synthetic Biology and Gene Editing to the industry and society. Current priorities are to: 1) Monitor and participate in public policy decisions affecting synthetic biology and gene editing 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[1]
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.