

## Introduction

The American College of Chest Physicians (CHEST), is committed to advancing best patient outcomes through innovative chest medicine education, clinical research, and team-based care. We are a member organization whose members are empowered to make themselves heard and to make a difference in chest medicine. CHEST leadership works diligently to ensure that CHEST addresses issues of concern for members, patients, and communities.

CHEST has a clear and explicit policy on conflict of interest for members holding a leadership position within the organization. Leaders regularly complete a disclosure form for review, supporting our value of transparency. As with bylaws, each time a change (amendment) is made to the policy, it must be formally approved and adopted by the Board of Regents. In addition, all leaders must request *a priori* review of new relationships.

To limit the potential for bias, CHEST enforces a strict leadership conflict of interest review and management process. While CHEST strives to appoint leaders, who are free from financial and/or intellectual conflict, the inclusion of recognized clinical experts who have relationships deemed to be manageable ensures the appropriate involvement of the leading scientists and clinicians in the field.

Accordingly, the Professional Standards Committee (PSC) will establish and maintain an Operations Document describing how disclosures are evaluated for COI and how resulting actions are determined and implemented.

### **Structure**

CHEST leaders are defined by five leadership levels: I, IIA, IIB, IIC, III. Each level is listed below, moving from most to least restrictive (left to right) with positions linked to those levels populating the corresponding columns.

		Level II		Level III		
Level I	Α	В	С	Leve	1 111	
President	President, CHEST Foundation	Chair and VC, Guidelines Oversight Committee	Deputy Editors, CHEST journal	Board of Trustee Members	Compensation Committee	
Immediate Past President	President- Designate	Chair and VC, Education Committee	Associate Editors, CHEST journal	Guideline Oversight Committee Members	Honor Lecture and Awards Committee	
President-Elect	Regents-at- Large	Chair and VC, Scientific Program Committee	-	Education Committee Members	Membership Committee	
Secretary (CHEST's EVP and CEO)	Chair and VC, Council of NetWorks	Immediate Past President, CHEST Foundation	-	NetWork Steering Committee Members	Scientific Program Committee Members	
Editor in Chief, CHEST journal	Chair, Executive Committee Council of Global Governors	President-Elect CHEST Foundation	-	Members of the Executive Committee of the Council of Global Governors and the Council of Global Governors	Scientific Presentations and Awards Committee	
Chair, Finance Committee	Joint CHEST/ATS Clinical Practice Committee	President- Designate, CHEST Foundation	-	NetWork members who participate in CHEST- sponsored activities	Social Media Work Group	
Governance Committee <sub>1</sub>	Governance Committee1	Professional Standards Committee	-	Editors, <i>CHEST</i> <i>Physician</i>	Training and Transitions Committee	
-	-	Governance Committee <sub>1</sub>	-	-	-	

<sup>&</sup>lt;sup>1</sup> The Governance Committee is slated from representatives among the Board of Regents and the Board of Trustees; thus, members will continue to adhere to the level assigned for their Board position of origin.

# **COI** Rules by Leadership Level

CHEST leaders are defined by five leadership levels: I, IIA, IIB, IIC, III.. Each level is defined below, moving from most to least restrictive.

**Level I.** Level I leaders are bound by the following COI rules during their term as Level I leaders:

- No promotional activities (see points of clarification below "A").
- Investigators in grant-funded research supported by nonprofit/government or commercial entity may receive funds, if directed to the institution. It is not acceptable to receive funds directed to the individual.
- Except for investments in mutual funds, no investments (e.g. holdings in stocks or stock options of pharmaceutical or device companies) or any other commercial entities that manufacture or sell products related to management of individuals with disorders addressed by CHEST. No investments in tobacco companies except for mutual funds. These restrictions apply to investments and intellectual property (e.g., patents associated with licensing, and/or financial or in-kind benefit) held by individual, their spouse, domestic or life partner, dependent children, and minors living in the same household (per IRS definition).
- Disclosure of any activities, investments, or employment of a spouse, domestic or life partner, dependent children, or minors living in the same household that may be affiliated with pharmaceutical companies or any other commercial entities (e.g., device manufacturers) that make or sell products related to management of individuals with disorders addressed by CHEST.
- No service as board member or officer of any other national or international medical or professional society (see points of clarification below "D").
- No service as chair of a committee or chair of any major projects (such as guidelines or consensus statements) of any other national or international medical or professional society, except for limited exceptions as authorized by the organization's decision-making body on COI. Serving as a committee member is permissible (see points of clarification "D" below).
- Disclosure of activities as a member of any committee of any other national or international medical professional society.
- No employment full-time, or part-time, is allowed for pharmaceutical companies or medical device companies.
- No consulting, or advisory board activity for pharmaceutical companies and medical device companies, including CHEST-sponsored focus groups, except as authorized by the organization's decision-making body on COI (see points of clarification A" below). This activity is not allowed even if it is not remunerated.
- No issuing statements on behalf of a commercial entity.
- No service as Editor in Chief of a journal (other than *CHEST* or *CHEST Physician*) in the field of critical care, pulmonary, or sleep medicine.

**Level IIA.** Level IIA leaders are bound by the following COI rules during their term as Level IIA leaders:

- No promotional activities (see points of clarification "A" below).
- Investigators in grant-funded research supported by nonprofit/government or commercial entity may receive funds, if directed to the institution. It is not acceptable to receive funds directed to the individual.
- Except for investments in mutual funds, no investments (e.g. holdings in stocks or stock options of pharmaceutical or device companies) or any other commercial entities that manufacture or sell products related to management of individuals with disorders addressed by CHEST. No investments in tobacco companies except for mutual funds. These restrictions apply to investments and intellectual property (e.g., patents associated with licensing, and/or financial or in-kind benefit) held by individual, their spouse, domestic or life partner, dependent children, and minors living in the same household (per IRS definition).
- No service as board member or officer of any other national or international medical or professional society (see points of clarification "D" below).
- No service as chair of a committee or chair of any major projects (such as guidelines or consensus statements) of any other national or international medical or professional society, except for limited exceptions as authorized by the organization's decision-making body on COI. Serving as a committee member is permissible (see points of clarification "D" below).
- Disclosure of activities as a member of any committee of any other national or international medical professional society.
- No employment full-time, or part-time, is allowed for pharmaceutical companies or medical device companies.
- No consulting, or advisory board activity for pharmaceutical companies and medical device companies, including CHEST-sponsored focus groups, except as authorized by the organization's decision-making body on COI (see points of clarification "A" below). This activity is not allowed even if it's not remunerated.
- No issuing statements on behalf of a commercial entity.
- No service as Editor in Chief of a journal (other than CHEST or CHEST Physician) in the field of critical care, pulmonary, or sleep medicine.

**Level IIB**. Level IIB leaders are bound by the following COI rules during their term as Level IIB leaders:

- No promotional activities (see points of clarification "A" below).
- Investigators in grant-funded research supported by nonprofit/government or commercial entity may receive funds, if directed to the institution. It is not acceptable to receive funds directed to the individual.
- Except for investments in mutual funds, no investments (e.g. holdings in stocks or stock options of pharmaceutical or device companies) or any other

commercial entities that manufacture or sell products related to management of individuals with disorders addressed by CHEST. No investments in tobacco companies except for mutual funds. These restrictions apply to investments and intellectual property (e.g., patents associated with licensing, and/or financial or in-kind benefit) held by individual, their spouse, domestic or life partner, dependent children, and minors living in the same household (per IRS definition).

- No service as board member or officer of any other competing national or international medical or professional society (see points of clarification "D" below).
- No service as chair of a committee or chair of any major projects (such as guidelines or consensus statements) of any other national or international medical or professional society, except for limited exceptions as authorized by the organization's decision-making body on COI. Serving as a committee member is permissible (see points of clarification below "D").
- No employment full-time, or part-time, is allowed for pharmaceutical companies or medical device companies.
- Consulting or advisory board activity for pharmaceutical companies and medical device companies, including CHEST-sponsored focus groups, except as authorized by the organization's decision-making body on COI (see points of clarification (C) below) is manageable.
- No issuing statements on behalf of a commercial entity.
- Disclosure of activities as a member of any committee of any other national or international medical professional society.
- No service as Editor in Chief of a journal (other than CHEST or CHEST Physician) in the field of critical care, pulmonary, or sleep medicine.

**LEVEL IIC.** Level IIC leaders are bound by the following COI rules during their term as Level IIC leaders:

- No promotional activities (see points of clarification (A) below).
- Investigators in grant-funded research supported by nonprofit/government or commercial entity may receive funds, if directed to the institution. It is not acceptable to receive funds directed to the individual.
- Except for investments in mutual funds, no investments (e.g. holdings in stocks or stock options of pharmaceutical or device companies) or any other commercial entities that manufacture or sell products related to management of individuals with disorders addressed by CHEST. No investments in tobacco companies except for mutual funds. These restrictions apply to investments and intellectual property (e.g., patents associated with licensing, and/or financial or in-kind benefit) held by individual, their spouse, domestic or life partner, dependent children, and minors living in the same household (per IRS definition).
- No service as board member or officer of any other competing national or international medical or professional society (see points of clarification (B) below).

- Service as a member or chair of a committee or chair of any major projects (such as guidelines or consensus statements) of any other national or international medical or professional society is permissible. However, Deputy and Associate Editors should maintain confidentiality regarding journal information and refer questions to the Editor in Chief.
- Disclosure of activities as a member of any committee of any other national or international medical professional society.
- No employment full-time, or part-time, is allowed for pharmaceutical companies or medical device companies.
- Consulting or advisory board activity for pharmaceutical companies and medical device companies, including CHEST-sponsored focus groups, except as authorized by the organization's decision-making body on COI (see points of clarification "B" below) is manageable.
- No issuing statements on behalf of a commercial entity.
- No service as Editor in Chief of a journal (other than *CHEST* or *CHEST Physician*) in the field of critical care, pulmonary, or sleep medicine.

**Level III**. Level III leaders are bound by the following COI rules during their term as Level III leaders:

- No relationships with tobacco companies.
- No employment full-time, or part-time, is allowed for pharmaceutical companies and medical device companies.
- Level III leaders may have conflicts but will have to rescue themselves from conversations related to those conflicts. These COIs are considered manageable.

#### Other Matters

- A. Effective date of implementation of these COI rules: October 18, 2019.
- B. Notification of the adopted policy will be sent to all members.
- C. Any questions or clarifications concerning a conflict are initially addressed by respective committee or other CHEST entity. However, if no immediate resolution is forthcoming, clarification is required, or continued concerns exist, the matter will be submitted to the Professional Standards Committee for a determination.
- D. A COI disclosure form for all CHEST leaders and staff is updated annually and available online.
- E. Committees should start every meeting (both remotely and in- person) by asking whether anyone has any new COI to disclose, including a COI related to a matter on the meeting agenda.

#### **Points of Clarification**

A. Please see the in <u>Appendix B: CHEST Conflict of Interest Terminology</u> for definitions related to promotional activity, speaker's bureau, etc.

In relation to commercial entities, the PSC refers to the ACCME definition of a commercial entity as an entity that produces, markets, re-sells, or distributes health care goods or services consumed by, or used on, patients. The ACCME does not consider providers of clinical service directly to patients to be commercial interests. For full detail, refer to Appendix B: CHEST Conflict of Interest Terminology (ACCME Commercial Entity)

- B. The restrictions on service for other professional medical societies intend to avoid risk or perception of conflicting loyalties that could impair CHEST and its best interests, and apply to national and international entities only. They do not limit a leader's participation in local and state medical and professional societies or in hospital management. Level IIB/IIC leaders may serve on the board for another society providing that it is not an organization with which CHEST would compete for members, annual meeting attendance, or products.
- C. The restriction on work for pharmaceutical and medical device companies might limit a leader's participation as a content expert for a company. Leaders who believe that their work for a company would not create an actual or perceived conflict of interest may seek formal authorization for an exception.
- D. Within the context of the restriction on serving as a board member for a national or international medical or professional society, "board" is considered to have a fiduciary responsibility. Committees with the name "board" that do not have fiduciary responsibility would not be considered as a conflict of interest.

#### **Appeals**

Any questions or clarifications concerning a conflict are initially addressed by the respective committee or other CHEST entity. However, if no immediate resolution is forthcoming, clarification is required, or continued concerns exist, the matter will be submitted to the Professional Standards Committee for a determination.

If the member disagrees with the determination of the Professional Standards Committee, the member may appeal the decision to a COI Appeals Committee consisting of the Chair of the Professional Standards Committee (serves as Chair), two Regents-at-Large appointed by the President, and the Immediate Past President serving as the liaison to the Professional Standards Committee. A super majority (3/4) is required to reach a decision, which will be binding.

### **Review and Categorization of COIs**

Disclosure of COIs over the last 3 years is required, including relationships in pulmonary, critical care, and sleep medicine, and areas where there may be a potential conflict, with the mission of CHEST, must be explained. This also includes activities relevant to practice, industry, or commercial entities that have products

related to pulmonary, critical care, and sleep medicine or overlap with the mission of CHEST.

If an individual takes on new non-CHEST related leadership appointments during the time as a CHEST leader, the COI disclosure must be updated. New external leadership appointments and relationships should be disclosed and approved by the Professional Standards Committee before the new position is accepted.

Questions regarding new leadership relationships may be sent to the Professional Standards Committee to ensure the new relationship adheres to CHEST policies.

For full detail, refer to Appendix A: Categorization of Relationships and Activities by Role.

**Appendix A:**Categorization of Relationships and Activities by Role

Type of Relationship/Activity		A Level I	B Level IIA	C Level IIB	D Level IIC	E Level III	
1	Authorship of scientific peer-reviewed publications	Acceptable	Acceptable	Acceptable	Acceptable	Acceptable	
2	Authorship of nonscientific publications	Acceptable	Acceptable	Acceptable	Acceptable	Acceptable	
3	Authorship of textbooks/chapters	Acceptable	Acceptable	Acceptable	Acceptable	Acceptable	
4	Authorship of material in support of a commercial entity	Disqualifying	Disqualifying	Disqualifying	Disqualifying	Situational Recusal	
5	Investigator in grant-funded research supported by nonprofit/government or commercial entity						
5.1	With funds directed to institution	Acceptable	Acceptable	Acceptable	Acceptable	Acceptable	
5.2	With funds directed to individual	Disqualifying	Disqualifying	Disqualifying	Disqualifying	Situational Recusal	

Type of Relationship/Activity		A Level I	B Level IIA	C Level IIB	D Level IIC	E Level III	
	EDUCATIONAL ACTIVITIES						
6	Faculty in CME-/MOC- accredited activity	Acceptable	Acceptable	Acceptable	Acceptable	Acceptable	
7.1	Faculty in commercially sponsored nonaccredited activity (i.e., morning symposia)	Disqualifying	Disqualifying	Disqualifying	Disqualifying	Situational Recusal	
7.2	Faculty in a commercially sponsored, nonaccredited activity where a not-for-profit organization fully controls speaker selection and content (e.g. CHEST-run commercially sponsored symposia)	Acceptable	Acceptable	Acceptable	Acceptable	Acceptable	
		ADVISORY/CON	SULTANCY ENG	AGEMENTS			
8	Participation in a data- safety monitoring board	Acceptable	Acceptable	Acceptable	Acceptable	Acceptable	
9.1	Advisor/consultant to industry on study design, education, or focus group	Disqualifying	Disqualifying	Manageable	Manageable	Situational Recusal	
9.2	Advisor/consultant to CHEST sponsored focus group by industry	Disqualifying	Disqualifying	Manageable	Manageable	Situational Recusal	
l		PUBL	IC STATEMENTS				
11	Issuing statements on behalf of a commercial entity	Disqualifying	Disqualifying	Disqualifying	Disqualifying	Situational Recusal	
12	Providing paid expert testimony on behalf of a commercial entity	Disqualifying	Disqualifying	Manageable	Manageable	Situational Recusal	
12.1	Providing paid expert testimony privately for noncommercial entity (e.g., private sector)	Acceptable	Acceptable	Acceptable	Acceptable	Acceptable	

Type of Relationship/Activity		A Level I	B Level IIA	C Level IIB	D Level IIC	E Level III		
	INTELLECTUAL PROPERTY AND INVESTMENTS							
13.	Patent holder or applicant	Manageable	Manageable	Manageable	Manageable	Situational Recusal		
14	Investment in mutual funds	Acceptable	Acceptable	Acceptable	Acceptable	Acceptable		
15	Investments (e.g. stock holdings, stock options, warrants, shares, bonds, or any other form of direct investment; not as part of a mutual fund) in pharmaceutical companies or any other commercial entities (e.g., device manufacturers) that manufacture or sell products related to management of individuals with disorders addressed by CHEST. See <a href="Appendix B">Appendix B</a> regarding commercial entities. ^							
		Disqualifying	Disqualifying	Disqualifying	Disqualifying	Situational Recusal		
		E	MPLOYMENT					
16	Full-time/part-time employment arrangement with a for profit commercial entity that manufactures or sells products related to management of individuals with disorders of the chest	Disqualifying	Disqualifying	Disqualifying	Disqualifying	Disqualifying		
	TOBACCO/E-CIGARETTE							
17	Investments or engagements with tobacco-related companies.	Disqualifying	Disqualifying	Disqualifying	Disqualifying	Disqualifying		

^ Item 15: These restrictions apply to investments and intellectual property (e.g., patents associated with licensing, and/or financial or in-kind benefit) held by individual, their spouse, domestic or life partner, dependent children, and minors living in the same household.

Type of Relationship/Activity		A Level I	B Level IIA	C Level IIB	D Level IIC	E Level III	
	PROFESSIONAL MEDICAL SOCIETY INVOLVEMENT						
18.1	Service as board member or officer of a competing	Disqualifying	Disqualifying	Disqualifying	Disqualifying	Situational Recusal	

	organization with which CHEST would compete for members, annual meeting attendance, or products.					
18.2	Service as board member or officer for another society provided that it is not an organization with which CHEST would compete for members, annual meeting attendance, or products.	Disqualifying	Disqualifying	Acceptable	Acceptable	Acceptable
19.1	Service as chair of a committee or chair of any major projects (such as guidelines or consensus statements) of a competing organization with which CHEST would compete for members, annual meeting attendance, or products.	Disqualifying	Disqualifying	Disqualifying	Manageable	Situational Recusal
19.2	Service as chair of a committee or chair of any major projects (such as guidelines or consensus statements) for another society provided that it is not an organization with which CHEST would compete for members, annual meeting attendance, or products.	Acceptable	Acceptable	Acceptable	Acceptable	Acceptable
20.1	Activities as a member of any committee of a competing	Manageable	Manageable	Manageable	Manageable	Situational Recusal

	organization with which CHEST would compete for members, annual meeting attendance, or products.					
20.2	Activities as a member of any committee of another society provided that it is not an organization with which CHEST would compete for members, annual meeting attendance, or products.	Acceptable	Acceptable	Acceptable	Acceptable	Acceptable
21	Service as Editor in Chief of a journal in the field of (other than CHEST or CHEST Physician) critical care, pulmonary, or sleep medicine.	Disqualifying	Disqualifying	Disqualifying	Disqualifying	Situational Recusal

# **Appendix B:**

CHEST Conflict of Interest Terminology (Developed October 2019)

**Commercial Advisory Boards, Committees, or Engagements**: Serving on a committee or board organized by a commercial entity on a topic related to a company project, product or promotion.

**Authorship:** Listed among the authors of a manuscript or other publication that is intended for distribution (first, middle or last author). Being listed in the acknowledgement section does not count as authorship.

**Commercial Educational Activity**: Educational forum organized/supported by a commercial entity without conformance to standards required by the American College of Continuing Medical Education (ACCME) (i.e. non-accredited). Examples include satellite symposia, pharmaceutical or device manufacturer organized educational events, local sponsored lectures, or any talk/presentation using any industry branded, generated, or facilitated slides.

## **Commercial Entity:**

The PSC defers to the ACCME definition of a commercial entity. A *commercial interest* is any entity producing, marketing, re-selling, or distributing health care goods or services consumed by, or used on, patients.

The ACCME does not consider providers of clinical service directly to patients to be commercial interests - unless the provider of clinical service is owned, or controlled by, an ACCME-defined commercial interest.

A commercial interest is not eligible for ACCME accreditation. Commercial interests cannot be accredited providers and cannot be joint providers. Within the context of this definition and limitation, the ACCME considers the following types of organizations to be eligible for accreditation and free to control the content of CME in which case they would not be considered commercial entities by CHEST:

- 501-C Non-profit organizations (Note, ACCME screens 501c organizations for eligibility. Those that advocate for commercial interests as a 501c organization are not eligible for accreditation in the ACCME system. They cannot serve in the role of joint provider, but they can be a commercial supporter.)
- Government organizations
- Non-health care related companies
- Liability insurance providers
- Health insurance providers
- Group medical practices
- For-profit hospitals
- For-profit rehabilitation centers
- For-profit nursing homes
- Blood banks
- Diagnostic laboratories

**Competing Organization**: Another society or organization with which CHEST would compete (e.g. for members, annual meeting attendance, or products).

**Conflict of Interest:** Any relationship or other known set of circumstances that has the potential to bias or might reasonably be perceived by others to bias, an individual's judgement, conduct or other actions.

- **Financial COI:** Any relationship for which one receives remuneration or inkind benefits that could be perceived to influence one's judgement in the evaluation of specific recommendations. These include relationships by the participant, their spouse, domestic or life partner, dependent children and minors living in the same household.
- **Intellectual COI:** Any activity that creates the potential for attachment to a specific predetermined point of view that could be perceived to affect one's judgement in the evaluation of specific recommendations or suggestions.
- Related content area: Those that are aligned with the clinical questions and/or PICO elements to be addressed within the guideline or recommendation.

**Consultancy:** Time-limited business relationship with a commercial entity, where the consultant provides professional input regarding a project, product, or medical topic. To comprise a COI, the consultant must receive some remuneration for their participation which includes in-kind payments such as travel expenses.

**Expert Testimony**: Testimony made by a qualified person about a scientific, technical, clinical, or professional issue. A key distinction is whether one provides testimony in support of (or opposition to) a pharmaceutical or device company (which must be managed or is prohibited, depending on one's leadership level/guideline position with CHEST) or for a patient which is acceptable.

**Employment:** Refers to a contractual arrangement where the employee performs a service which is paid for by the employer.

Faculty: Presenter or moderator at an educational or promotional event

**Guideline Panelist:** Any person who contributes to the work of developing the guideline (e.g. defining the scope, forming the clinical questions, searching and evaluating the literature, developing recommendations or suggestions, voting, and drafting the manuscript) and includes an expectation of authorship, provided they meet the criteria defined by the International Committee of Medical Journal Editors.

**Investigator**: Investigators on a project usually receive remuneration for their role on the program/project. This typically includes Principal Investigators and Co-Investigators, but not consultants (paid or unpaid). Forms of remuneration include monetary compensation, equipment, travel, or supplies.

**Speakers Bureaus**: Being identified as a company sponsored speaker for an educational event where slides or content are at least in part supplied by the company

If Pharma gives money to an institution or not-for-profit organization
 (assuming that organization is not financially linked to a pharmaceutical or
 device manufacturer) to host an event, it is required that the talk title, the
 talk content, speakers, and all funds be negotiated and managed by the
 institution/organization

**Patent Holder or Applicant**: Being listed as the sole or one of several inventors of some disclosed intellectual property submitted for patent consideration.

**Promotional Activities:** Those activities that support, market, or increase sales or consumption of a specific drug, device, technology, or technique, or that are intended to enhance the image, well-being, stature or popularity of a commercial entity pertinent to chest medicine, independent of remuneration.