



Society for Maternal-Fetal Medicine Special Statement: Society for Maternal-Fetal Medicine's conflict of interest policy

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A vital mission of the Society for Maternal-Fetal Medicine is to provide independent, objective, scientifically based information and recommendations for providers, patients, and payors of high-risk pregnancy care. To ensure that these recommendations are free from bias, special interest, or the perception of either, a publicly transparent process for disclosing relevant financial and nonfinancial interests (disclosures of interest) and management of potential conflicts of interest are essential. Educational and research presentations also require proper disclosure to allow attendees to properly assess information presented at the Society for Maternal-Fetal Medicine events. The Society for Maternal-Fetal Medicine established a task force to review the current Society for Maternal-Fetal Medicine policies and procedures as they pertain to disclosure of interest and conflict of interest. To establish current best practices in disclosure of interest and conflict of interest definitions, reporting, and conflict of interest mitigation, members of the task force reviewed external literature, including policies of other medical organizations. The Society for Maternal-Fetal Medicine is committed to a continuous process of improvement in the approach to these issues and will revise this policy as indicated.

Key words: conflict of interest (COI), disclosure of interest (DOI)

Introduction

A healthcare-related disclosure of interest (DOI) is a signed declaration that includes both financial and intellectual interests related to healthcare. It does not assume that a disclosed interest represents an actual conflict of interest (COI). A COI is defined as any declared interest that could affect, or might reasonably be perceived to affect, objectivity and independence such that the individual's primary actions on behalf of the Society for Maternal-Fetal Medicine (SMFM) could be perceived as motivated by secondary financial gain, academic or professional advancement, or improvement of community standing.^{1–3}

A rigorous and definable process for DOI and management of COIs are central to the work of any organization that produces guidelines, publications, educational meetings, and deliberative processes like SMFM. The goal of this administrative practice is to eliminate any potential biases to ensure public trust and credibility.

Background and methods

In the spring of 2019, SMFM established a task force to evaluate current DOI and COI policies and procedures for

SMFM. The task force reviewed current literature on the topic of COI, including current trends, best practices,^{1–26} policies, and position papers on COI from other medical societies,^{2–4,21,25} and discussed challenges regarding COI policy development and implementation for SMFM. After a review of available literature and multiple discussions, a policy for COI was developed for SMFM to provide clarity and improve public transparency. Because enforcement and review of the policies are an ongoing process, the task force recommended the establishment of a committee on COI by the task force chair, and its origination was approved by the SMFM Executive Committee to adjudicate unsettled or questionable COI issues for SMFM and to provide an ongoing review of COI policies and procedures for SMFM.

Goals and principles

By providing a path for thoughtful examination, guidance, and remediation of DOI and COI, the task force's goal is to preserve and further enhance professional and public trust in the Society's guidelines, statements, research and educational presentations, and other endeavors. The purpose of a COI statement is not to declare bias, but to provide transparency to Society members, stakeholders, governmental agencies, public organizations, and patients. Volunteer members of SMFM make valuable contributions to the Society, its stakeholders, and patients, bringing a

TABLE 1

COI management recommendations for participants in the writing and development of SMFM-branded guidelines and materials

| Level | Example of disclosure | Actions | Management |
|-------|---|-------------------------------------|---|
| A | (1) Income from seminars, lectures, or teaching engagements that do not have a commercially vested interest in the specified topic (2) Service (paid or unpaid) on advisory committees or review panels (public entities, nonprofit organizations, or otherwise) that do not have a vested interest in the specified topic (3) Service on unpaid advisory panels in service of SMFM or Foundation for SMFM (4) Employment from nonprofit organizations (such as government agencies, other public entities, and nonprofit organizations) that do not have a vested interest in the specified topic (5) Ownership of topic-related stocks with a total value of <\$1000 (6) Other financial compensation (direct compensation, funding for research, or otherwise) from a relevant entity <\$1000 over a 3-year period. "Other compensation" includes incidental compensation such as dinners, paid speaking engagements, and other consultative work. (7) Topically relevant service, advocacy, or lobbying activity on behalf of a healthcare or disease advocacy organization (8) Serving as an editor or deputy editor of an academic journal, book, or website | No restrictions | (1) Participant is not restricted in any way from participation, including discussion, voting, authorship, or review roles. |
| B | (1) Funding from a relevant entity for research investigations (clinical or otherwise) of \geq \$1000 over a 3-year period (2) Individual topic-specific public comments, expert testimony, or participation in speaking engagements (excluding those on behalf of a relevant entity) (3) Participation in any governmental organizations, professional societies, or other organizations related to the topic of interest (4) The participant has one or more primary author publications or research grants that are likely to be part of the evidence review or that address key questions in the analytical framework or that express opinions related to the topic. | Participant is partially restricted | (1) Member may participate in initial discussions related to a topic and the initial writing process. Thereafter, the member may contribute to ongoing discussions in the editorial process but will not be responsible for further acceptance or denial of edits beyond the initial product. |

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(continued)

diversity of demographics, opinions, and practice types. The main principles of SMFM's COI policy are as follows:

- COI can alter the perceptions of statements, guidelines, policies, and intent of SMFM leadership and their educational efforts.
- Concerns regarding COI are generally situational and not indicative of personal conduct, character, or actions.
- Chairs, organizers, and leaders of official SMFM activities should routinely request and evaluate the disclosures of potential participants and apply established paths for resolution of potentially relevant COI.
- Members and significant participants in SMFM leadership and educational activities should be notified of other participants' DOI and COI before participating in activities or deliberations.
- In the final products, documents, statements, or activities of SMFM, transparency should be exhibited, and the process of DOI and COI management must be acknowledged.³

After a review of the current SMFM COI policy, the task force identified the following **key goals** incorporating the principles outlined earlier:

- Develop a policy on COI that is publicly accessible.** Consistent with the United States Preventive Services Task Force statement on COI, transparency and public accessibility to COI policies are critical.²¹ The SMFM COI Task Force recommended a publicly accessible COI policy be made available and referred to in all SMFM-branded publications. Although some members supported public access to all disclosures made by individuals serving SMFM, the balance of task force members thought that this form of

TABLE 1

COI management recommendations for participants in the writing and development of SMFM-branded guidelines and materials (*continued*)

| Level | Example of disclosure | Actions | Management |
|-------|---|--------------------------------------|---|
| C | <ol style="list-style-type: none"> (1) Ownership of topic-related stocks with a total value of $\geq \\$1000$ (not including blind trusts, mutual funds, or exchanged traded funds over which the individual has no financial control) (2) Topic-specific public comments, paid speaking engagements, etc, on behalf of a relevant commercial entity (3) Topic-specific relevant entity funding of $\geq \\$1000$ over a 3-year period not related to research, clinical investigations, or studies conducted in accordance with federal requirements. This funding includes incidental compensation such as dinners, paid speaking engagements, and other consultative work. It also includes funding for work performed by the individual in which funding of $\geq \\$1000$ is provided to the practice, division, department, or other entity that employs the individual in question. (4) Benefit, service, or position with any relevant commercial entity (as an officer, board member, medical director, corporate speaker list, expert legal testimony, expert advisor, or paid consultant [beyond travel and related room and board expenses] or receipt of fiduciary fee, limited liability company fee, loan, manuscript fee, officer fee, partnership, patents, or nonbook-related royalty) related to the specific topic (5) Participation as an author of or a significant contributor to a publication that has necessitated a focused SMFM publication or guidance on that specific publication. The participant is noted as a primary topic expert with opinions that are likely to be a major part of the evidence review. | Participant is recused for the topic | <ol style="list-style-type: none"> (1) Member is recused from all topic-related meetings and discussions (in-person, phone, or electronic communication) and all writing, editorial, and final review activities and will not vote on the subject matter. (2) Publicly released recommendations will denote the member's recusal from participation and voting on this topic (eg, if a member on a standing committee where participation would be otherwise expected). (3) If a participant is able and willing to dissolve or release the relevant interests, the COI can be revisited and downgraded. |

This table presents examples of classification of DOIs with guidelines for management options of COIs. Examples listed do not represent the entire breadth of reportable DOIs and potential COIs or their eventual adjudication. SMFM participants are expected to disclose all interests regardless of whether they require an assigned level of conflict. Many DOIs do not require an assigned level of conflict and, as such, have no associated actions or implications.

COI, conflict of interest; DOI, disclosure of interest; SMFM, Society for Maternal-Fetal Medicine.

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disclosure was not considerate of members' privacy. A compromise of public declaration of any COI (level B or C) (Table 1), with a reporting of both the DOI and COI and steps taken to resolve the conflict, will be included in any SMFM-branded publication, guidelines, or communications.

2. **Provide clear definitions and disclosure practices for SMFM members serving SMFM regarding both financial and nonfinancial COIs.** The COI policy contained herein provides definitions of both financial and nonfinancial COIs. Although there is a universal agreement about the potential for an individual's (or family member's) financial interest to introduce a COI, there is no consensus regarding definitions or thresholds in the existing literature. A generally observed trend is toward lower reporting thresholds for financial disclosures, with some organizations and institutions adopting a threshold of \$0, because even small payments may compromise decision-making.^{6,13,17} The proposed thresholds for SMFM financial disclosures (Table 1, Table 2, Table 3)

attempt to balance the need to understand a member's (or family member's) relevant financial interests vs the burden of increased administrative duties for an individual. The task force members acknowledge that thresholds are largely subjective.

The task force members held a more challenging discussion regarding nonfinancial COIs. Recently, increased attention has been given to nonfinancial COIs and their potential influence, particularly in the development of professional society guidelines and statements.^{2,18,21} Unfortunately, nonfinancial COIs can be broadly described without clear evidence to define those nonfinancial DOIs that constitute a potential COI. In a review of nonfinancial COIs, descriptions have included previous public comments; leadership on other committees or panels; career efforts and interests; previous policy positions; competing beliefs, academic institutions, and societies; previous publications; or other intellectual conflicts, including authorship or grant funding related to a topic.²⁰ Because data in this

TABLE 2
COI management procedures for SMFM Board of Directors, Executive Committee, committee chairs, COI Committee members, SMFM Senior Executive Team, and CEO in the performance of SMFM-specific duties

| Level | Example of disclosure | Actions | Management |
|-------|--|--|--|
| A | <ol style="list-style-type: none"> (1) Income from seminars, lectures, or teaching engagements that are not for relevant commercial entities (2) Unpaid service on advisory committees or review panels of public entities, nonprofit organizations, or otherwise that do not have a vested interest in the specified topic (3) Ownership of a single stock in a relevant entity whose total value is <\$1000 (4) Employment from nonprofit organizations (such as government agencies, other public entities, and nonprofit organizations) that do not have a vested interest in the specified topic | No restrictions | <ol style="list-style-type: none"> (1) Participant is not restricted in any way from participation, including discussion, voting, authorship, or review roles. |
| B | <ol style="list-style-type: none"> (1) Funding from a relevant commercial entity for research investigations (clinical or otherwise) of ≥\$1000 within the previous 3-year period on a specific topic | Participant partially restricted | <ol style="list-style-type: none"> (1) Member will disclose verbally and in DOI form on any topic-related meetings, discussions, or activities. (2) For any guidelines, statements, or SMFM-branded materials, the member may participate in initial discussions related to a topic and the initial writing process. Thereafter, the member may contribute to ongoing discussions in the editorial process but will not be responsible for further acceptance or denial of edits beyond the initial product. (3) If a participant is able and willing to dissolve or release the relevant interests, the COI can be revisited and downgraded. |
| C | <ol style="list-style-type: none"> (1) Relevant commercial entity funding of ≥\$1000 over a 3-year period not related to research, clinical investigations, or studies conducted in accordance with federal requirements, including incidental compensation such as dinners, paid speaking engagements, and other consultative work (2) During the period of service, receipt of a benefit, service, or position with any relevant entity (as an officer, board member, medical director, corporate speaker list, expert legal testimony, or expert advisor or receipt of fiduciary fee, limited liability company fee, loan, manuscript fee, officer fee, partnership, patents, or nonbook-related royalty) (3) Current participation on an executive board or board of directors of another medical Society board with substantial overlap (eg, ACOG, PQF, SRI, and AGOS) (4) Ownership of a single stock in a relevant entity ≥\$1000 (not including blind trusts, mutual funds, or exchange-traded funds over which the individual has no control) | <p>Participant is recused from topic-related activities.</p> <p>Participant will terminate or divest in activities to potentially assume or continue with SMFM position.</p> | <ol style="list-style-type: none"> (1) Participant will eliminate all future paid activities with the relevant commercial entity. (2) Participant will resign from the activity causing the COI and cease activity and divest of any financial interest. COI can be revisited and downgraded with review by the COI Committee and the Executive Committee for final disposition on participant involvement. |

This table presents examples of classification of DOIs with guidelines for management options of COIs. Examples listed do not represent the entire breadth of reportable DOIs and potential COIs or their eventual adjudication. SMFM participants are expected to disclose all interests regardless of whether they require an assigned level of conflict. Many DOIs do not require an assigned level of conflict and, as such, have no associated actions or implications.

ACOG, American College of Obstetricians and Gynecologists; AGOS, American Gynecological and Obstetrical Society; CEO, chief executive officer; COI, conflict of interest; DOI, disclosure of interest; PQF, Perinatal Quality Foundation; SRI, Society for Reproductive Investigation.

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TABLE 3

Conflict of interest management procedures for presentations by SMFM-appointed speakers at SMFM-sponsored meetings or scientific presentations at annual or other SMFM events

| Speaker type | Type of disclosure | Description of transparency |
|---|--|--|
| Appointed speaker at SMFM-sponsored meeting or Pregnancy Meeting presentations or other SMFM scientific meetings (both oral and poster presentations) | <ol style="list-style-type: none"> (1) Topic-related relevant entity compensation of $\geq \\$1000$ (2) Ownership of topic-related stocks of any value (not including blind trusts, mutual funds, or exchange-traded funds over which the individual has no control) (3) Receipt of a benefit, service, or position with any relevant entity (as an officer, board member, medical director, corporate speaker list, expert legal testimony, or expert advisor or receipt of fiduciary fee, limited liability fee, loan, manuscript fee, officer fee, partnership, patents, or nonbook-related royalty) (5) Topic-related grants (6) Service (paid or unpaid) on advisory committees or review panels (public entities, nonprofit organizations, or otherwise) that have a vested interest in the specified topic (7) Employment from nonprofit organizations that have a vested interest in the specified topic (8) Ownership of topic-related stocks of any value (not including blind trusts, mutual funds, or exchange-traded funds over which the individual has no control) (9) Topic-specific public comments, speaking engagements, etcetera, on behalf of a relevant commercial entity (10) Participation in any governmental organizations, professional societies, or other organizations related to the topic of interest (11) Significant, nonfinancial interest in a specific outcome of a recommendation statement (12) Topically relevant service, advocacy, or lobbying activity on behalf of a healthcare, patient, or disease advocacy organization | DOI will be reviewed by a course director for SMFM-sponsored meeting after an invitation to present, and speaker must disclose COI at the beginning of a presentation. Must disclose COI at the beginning of an oral presentation or list on poster at the time of meeting presentation. |

This table presents examples of classification of DOIs with guidelines for management options of COIs. Examples listed do not represent the entire breadth of reportable DOIs and potential COIs or their eventual adjudication. SMFM participants are expected to disclose all interests regardless of whether they require an assigned level of conflict. Many DOIs do not require an assigned level of conflict and, as such, have no associated actions or implications.

COI, conflict of interest; DOI, disclosure of interest; SMFM, Society for Maternal-Fetal Medicine.

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area are limited, task force members often disagreed about what constitutes a nonfinancial COI but agreed with the principle on disclosure and mitigation of nonfinancial interests within the context of an already robust review process.

3. Establish guidelines for COI management. The task force proposed a process for resolving and adjudicating COIs to provide consistency about COI for members and the public. Although the inclusion of this information is not seen across all COI policies for other organizations, the task force members believed that this additional transparency, consistency, and accountability to the process of COI evaluation and management would benefit both the public and SMFM members who serve, or are considering serving, within the SMFM organization.

As with disclosures, the task force found it more difficult to come to a consensus regarding the appropriate

management of nonfinancial COIs. The task force debated the conflation of expert experience in a topic (and the conflict or bias such experience may present) with the goal of developing high-quality practice guidelines for SMFM. It is recognized that Society members have special expertise that is important to the development of practice guidelines. The task force proposed that establishing ground rules to manage any relevant nonfinancial COI surrounding the inclusion of such expertise would minimize the potential for an attachment to a specific point of view that could unduly affect specific recommendations. For focused topics with recommendations to be made after the publication of new research, it was generally agreed that authors participating in the research should be recused from writing or formal editing of guidelines. Examples of this concept would be the SMFM statements on the Randomized Trial of Induction vs Expectant Management trial (2018), late preterm administration of corticosteroids (2016), and 17-alpha hydroxyprogesterone caproate (2019). Of note, this clarification codifies the current policy of the Publications Committee. A

summary of actions to be undertaken to mitigate the perception of nonfinancial COIs was outlined in the COI policy to address the concerns that were raised during task force discussions about this issue. An important discussion point was clarifying the role of individual members within any policy or guideline writing group. Consistent with the American College of Physicians and other societies, a proposed suggestion to this situation was that although an expert (or participant with other relevant nonfinancial DOI) may contribute to discussions related to a topic and the initial writing process, they should be excluded as the controlling arbiter of the editorial process in the final draft. This action would be in addition to the extensive process and mitigation policy already in place for the development of SMFM guidelines and publications (Appendix 1 and Box), which includes a robust review by members of the committee that produces the document, the Document Review Committee, and the Executive Committee of the Board.

4. **Establish a committee to adjudicate any COI issues for SMFM and provide an ongoing review of COI policies and procedures with, at a minimum, yearly updates.** SMFM COI Task Force members concluded that to maintain a current DOI and COI policy that reflects national trends and seeks to maintain best practices for DOI and COI, a COI committee should be established, and this proposal was accepted. The goal of the COI Committee is to continue to update the SMFM policy on COI with a review at least annually. In any case in which it is unclear to a determining individual about the level of COI that should be assigned, the individual should consult the COI Committee. However, the task force felt that committee chairs, task force chairs, and program chairs should be the initial arbiter of guidelines and be familiar with this report. In addition, the COI Committee will help adjudicate any referred complex COI issues. This committee will report directly to the Executive Committee and submit an annual report. In addition, future tasks assigned to the COI Committee for advancement on this topic include the development of SMFM societal guidelines for improvement of organizational transparency in its relationships with commercial entities.

Society for Maternal-Fetal Medicine policy: disclosure of interest and conflict of interest

[The following text represents the official wording of the SMFM policy on DOI and COI management. This policy was established through the SMFM COI Task Force (see Appendix 2 for a list of task force members). This policy and document were approved by the SMFM Executive Committee, Publications Committee, and Document Review Committee in 2020.]

A rigorous process for DOI and management of COIs is central to the work of SMFM, including the production of

BOX

COI language used

COI language in SMFM-branded publications or materials:

“All authors and committee members have filed a disclosure of interests delineating personal, professional, business, or other relevant financial or nonfinancial interests in relation to this publication. Any substantial conflicts of interest have been addressed through a process approved by the Society for Maternal-Fetal Medicine (SMFM) Board of Directors. SMFM has neither solicited nor accepted any commercial involvement in the specific content development of this publication. Please refer to the separate policy on ‘Guidelines for the Development of SMFM Publications’ for details related to the process of guideline and publication development, editing, and review.”

COI language for the SMFM website:

“All members of the SMFM Board of Directors and committee members have filed a disclosure of interest with the Society for Maternal-Fetal Medicine. Any conflicts of interest have been resolved through a process approved by the Board of Directors.”

COI language for email reviews of draft manuscripts (Publications Committee, Risk Management, and Executive Committee):

“If you have any new or potential disclosures of interest not previously reported, please contact the chair and committee staff.”

COI, conflict of interest; *SMFM*, Society for Maternal-Fetal Medicine.

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high-quality, unbiased guidelines and publications, along with providing transparency in presentations and education. To achieve this objective, SMFM has developed a policy in which all COIs must be identified through a standardized DOI process and eliminated or managed in a manner that maintains objectivity while serving the Society and upholding the public trust.

All SMFM participants, as defined below, must self-declare healthcare-related interests. The COI Committee helps adjudicate any referred complex COI issues and reports these cases to the Board of Directors while maintaining the confidentiality of the relevant SMFM participants as appropriate. The COI Committee is also responsible for updating this policy.

Definitions

A **healthcare-related disclosure of interest (DOI)** is a signed declaration that includes financial, intellectual, or other

interests related to healthcare and does not assume that a disclosed interest represents an actual COI.

A **conflict of interest (COI)** is any professional or private interest that could affect or might reasonably be perceived to affect objectivity and independence such that the individual's primary actions on behalf of the Society could be motivated by secondary gain (financial, academic, professional, or otherwise).

An **official SMFM activity** includes serving the Society in an official capacity, such as leadership (SMFM Board of Directors) or committees; development of SMFM-branded documents (author, reviewer); participating in SMFM-branded projects (conferences, workshops, courses, task forces, special committees); or serving as a moderator, speaker, or judge for an SMFM meeting.

An **SMFM participant** may be a member of the Society or an invited or elected participant in SMFM-branded activities. Participants include but are not limited to 1) members of the SMFM Board of Directors, standing committees, ad-hoc committees, and task forces; 2) chairs, organizers, and participants of SMFM-branded conferences or educational courses; 3) participants in the development, implementation, or both of any SMFM-branded publication or product; 4) volunteer or hired SMFM staff; and 5) invited primary authors or reviewers.

A **relevant commercial entity** includes but is not limited to any institution, company, corporation, partnership, firm, association, or organization external to the Society that might have a financial or business interest in being associated with the Society, its members, or participants. These interests extend to those gained as a result of a relationship with an official SMFM activity or of specific knowledge provided by an SMFM participant that could benefit that entity. Such entities could include but are not limited to those in the pharmaceutical, biotechnology, medical device, or insurance businesses.

Other organizations refers to non-SMFM organizations in which SMFM members may participate in a leadership capacity (such as serving on a committee, board of directors, organizer, liaison, task force, or any other specific member capacity). SMFM members who have a leadership role or participant role in the development of guidelines or written work within SMFM must disclose their involvement in such roles within other organizations. Final written products of SMFM also should disclose these roles. However, societies that are asked to cobrand, endorse, or participate in SMFM documents and have a COI and DOI policy are not required to submit a DOI or COI statement as long as they have complied with such policies for the organization they represent.

Who reports disclosure of interest?

Any person serving as an SMFM participant in an official SMFM activity is required to disclose potential COIs, excluding abstract reviewers and judges for the annual Pregnancy Meeting. Because of the large number of abstract reviewers and judges for the Pregnancy Meeting,

these participants will be given written instructions to recuse themselves for possible COI. All other participants must report any healthcare-related interests for themselves and their family members, including current spouse (including common law), life partner, dependent children, or persons cohabitating with the SMFM participant greater than or equal to 1 year.

What is the time frame for disclosure of interest?

The time frame for reporting healthcare-related interests is the previous 3 years and any interests anticipated in the subsequent year.

When is the disclosure of interest collected?

All prospective participants proposed to serve the Society in an official capacity must complete a DOI form before participation in any SMFM activity and before consideration for board positions. Ongoing participants must update their DOI on an annual basis. All SMFM participants must disclose to the Society, including the committee chair of any relevant committee or task force, any new financial or nonfinancial interests as they arise (within 90 days) or before publication of an SMFM-branded publication. SMFM staff and the committee chair are expected to prompt SMFM participants to review and update their DOI before and during the development of SMFM-branded products and before publication. The Executive Committee, because of their additional role in editorial processes, will be asked to update their DOI statements semiannually.

What disclosures of interest are required from participants?

Participants must disclose active (current participation) and inactive (past participation within the previous 3 years) financial and nonfinancial interests ([Appendix 3](#) for definitions).

Financial disclosure of interest and conflict of interest

A financial COI is one that creates a risk that professional judgments or actions could be unintentionally influenced by an individual's financial secondary gain rather than upholding the primary interest of the integrity of SMFM's through its professional activities. Situations in which relevant healthcare entities or organizations might profit from the conclusions of a guideline or publication present a substantial risk of actual or perceived bias. Potential financial interests that must be disclosed include but are not limited to the following:

- Stocks, stock options, or other equity positions (excluding those as part of a broadly diversified investment such as a mutual fund)
- Paid consulting work, speaking bureau participation, honoraria, expert witness testimony, or testimony in

support of the healthcare industry or professional organizations. Direct payments to the individual or indirect payments for any of the above activities to a practice, hospital department, or university department or division shall be considered as payment to the individual

- Research grants and contracts, including those from federal, foundation, and relevant commercial entities
- Patents
- Employment relationship with an entity that could be financially or reputationally affected by an SMFM decision or position
- Involvement in a proprietary company such that the SMFM participant could gain financially from the outcome of the SMFM activity, eg, becoming a board director, medical director, or similar position.

Nonfinancial disclosure of interest and conflict of interest

Preservation of trust in SMFM's professional activities also requires that nonfinancial (intellectual) COIs be considered and addressed with appropriate rigor to ensure organization, stakeholder, and public trust and transparency. A nonfinancial COI is defined as 1) any belief, position, or attachment to ideas or activities related to a topic area where there is the potential for a reasonable person to question the possibility of bias on the part of an SMFM participant related to work on a specific task (for example, a publication, guideline, or task force) or 2) any non-SMFM-related nonfinancial relationship with relevant commercial entities (such as vendors), advisory boards, governmental organizations, healthcare organizations, or professional societies that may benefit or be harmed by official SMFM recommendations. SMFM activities susceptible to nonfinancial COIs are those that are content-related or focused, including but not limited to guidelines development, publications, and participation in a specific content-focused task force. Because nonfinancial COIs are typically specific to a given topic, disclosure before commencing content-specific SMFM activities is required.

Examples of nonfinancial interests that could constitute a potential COI and require disclosure include but are not limited to:

- Previous public comments, testimony, or positions on a topic for relevant commercial entities
- Research grants or funding
- Key role in or affiliation with research on a topic that is related to a guideline, publication, statement, or other product or activity. Key roles include first, second, or senior authorship and principal investigator designation for multicenter research
- Expert testimony benefiting a relevant commercial entity
- Service on an advisory board or in the service of other relevant commercial entities that are not SMFM- or Foundation for SMFM-related roles (unfunded roles)
- Leadership role on a panel held by a relevant entity

- Advocacy or policy positions previously written on behalf of a relevant entity.

What disclosures are not required?

The task force also provided guidance on what activities do not require disclosure. These activities include ownership of a blind trust, holding stocks within diversified mutual funds or retirement funds, general membership activities in professional societies, attendance at presentations or conferences related to the topic of interest, and legal testimony related to medical malpractice. The task force recognized that individual experiences and viewpoints might be sources of nonfinancial bias, including within the political, religious, or ideological domains, but believe, as do other professional organizations, that it is not reasonable or practical to assess them owing to privacy concerns. However, participants should use their own judgment about additional interests that might be pertinent for disclosure.

How are interests disclosed?

Participants in SMFM activities must complete a standardized, structured electronic form with close-ended questions designed to elicit all healthcare-related DOI in accordance with the Sunshine Act. Participants will sign and date this form, thereby certifying that to the best of their knowledge, they have disclosed their financial and nonfinancial COIs and will promptly report any changes by completing, signing, and dating a new form.

Assessment of disclosure of interest and identification of conflicts of interest

Each SMFM participant (prospective or ongoing) serving in an official capacity shall undergo screening for potential COIs by a review of their DOI before participating in any relevant SMFM activities, before initiating a new topic-related activity, and at least annually. The committee chair, task force chair, or leader of any group representing SMFM in a formal capacity is primarily responsible for reviewing DOIs. The goal of this review is to identify any COI for the members of their working group or initiative, including but not limited to the designated leader responsible for standing committees, ad-hoc committees, and task forces; invited or elected participants in SMFM-branded conferences and educational courses (course directors); participants in the development and implementation of any SMFM-branded publication or product; and invited primary authors and consultants. Members of the SMFM Board of Directors, committee chairs, COI Committee members, SMFM Senior Executive Team, and the SMFM CEO will submit their DOI annually to the SMFM CEO and SMFM President for review for potential COIs.

Appointed speakers will provide a DOI to identify COI issues to the course director upon appointment to any SMFM-branded public educational or presentation activity. If an appointed speaker or Pregnancy Meeting presenter does not follow these guidelines, the course director or

program chair, and, if deemed necessary, the COI Committee, should be notified.

Each DOI will be assigned a level of involvement (below) using a tiered system. This tiered scheme is similar to those of other organizations to describe the potential level of a specific COI.^{2,21} The spectrum of COI involvement includes:

- A disclosure with no COI
- Level A COI: a disclosure with no action required
- Level B COI: a disclosure in which an SMFM participant is partially restricted from participation in the activity, depending on the significance of the conflict and relevance to the given topic; and
- Level C COI: a disclosure in which an SMFM participant is substantially restricted or recused from participation.

The SMFM COI Committee is an available resource for any DOI or COI issues that require additional assistance, and a referral can be made as needed or appropriate.

Levels of conflicts of interest

Level A conflicts of interest

A level A COI includes substantial inactive relationships that were ended <3 years before engaging in work as an SMFM participant. This definition allows for participation if individuals are able and willing to terminate such relationships or divest themselves of future profit or gain related to those relationships within the appropriate timeline. Ownership of individual stocks valued at <\$1000 in relevant entities also constitutes a low-level COI. General employment with a nonprofit organization (excluding topically related disease advocacy groups, non-SMFM medical organizations, and other nonprofit organizations that could qualify for a higher level of conflict) does not constitute a COI. Nonfinancial low-level COIs include those that are not related directly to the specific topic.

Level B conflicts of interest

A level B COI is most often a nonfinancial relationship (such as an intellectual interest) to a relevant entity that is germane to a topic (often underdiscussion for development of guidelines or clinical practice recommendations), in which the relationship or intellectual interest to the relevant entity may create the opportunity for bias (cognitive or other) to influence formal SMFM recommendations, guidelines, or publications.

Often unintentional or unconscious, several types of cognitive bias can manifest during the development of SMFM-branded clinical guidelines, publications, educational conferences, and other products and activities. These include but are not limited to confirmation bias (the inclination to interpret or disregard new evidence in favor of validating existing beliefs or theories) or authority bias (the tendency to give greater weight or uncritical acceptance to the opinions of experts, including oneself). Because perceived expertise may exert significant influence over the

conclusions of clinical guidelines, it is appropriate and necessary to assess intellectual interests to balance their influence and opinion.

Proposed actions that address these issues at the Society level to mitigate nonfinancial COIs when convening a topic or content-specific activity are listed below (see “How are conflicts of interest managed?”). The primary objective of managing nonfinancial level B COIs is not to exclude experts from participating in SMFM activities altogether, which would be an unintended negative consequence. Rather, the goal is to minimize perceived or actual bias and balance input into the development of SMFM guidelines and other publications.

Level C conflicts of interest

A level C COI is any active, current relationship (financial or otherwise) between an SMFM participant and a relevant entity that has the potential to directly influence the work of SMFM for the direct gain of the SMFM participant or relevant entity. Most often, this level of COI is exemplified by a relevant entity or SMFM participant that has a direct financial stake in the clinical conclusions of a guideline or guidance statement. Relevant entities that pose the highest risk include pharmacologic, biotechnology, medical device, and insurance companies. Such relationships include those in which the SMFM participant serves as a board member, medical director, officer, partner, speakers' bureau member, or paid consultant (beyond travel and reasonable lodging and meals) or receives fees directly or indirectly (for example, to a practice, division, or department) for manuscripts, expert testimony, royalties, or grant funding from relevant entities. Conflicts of this nature are often not limited to isolated topics owing to the fluidity of the corporate landscape with mergers and acquisitions and changing product portfolios, which often makes it difficult to assess the level of the perceived or actual COI over time.

Specific disease advocacy organizations also have the potential to be increased-risk entities because of their financial relationships with industry and the public. Many of these organizations rely on fundraising, which often involves industry support; may favor or promote certain screening, diagnostic, and treatment practices; and receive money from donors, who may exert influence. These relationships outside of activities sanctioned by SMFM or the Foundation for SMFM may create circumstances that diminish scientific objectivity and creates the potential for COI and should be disclosed. Nonetheless, advocacy relationships with specific disease advocacy organizations by individuals should generally be considered as level A COI unless financial relationships present a further concern for COI.

How are conflicts of interest managed?

It is important to recognize that management of COIs does not end with the disclosure of sources of potential bias. Not all COIs carry similar perceived risk. Therefore, the management plan must be proportional to the level of the COI.

Each level has a set of possible actions that may be applied to manage the COI. Management options are outlined in [Table 1](#) (for participants in committees or groups producing SMFM-branded materials), [Table 2](#) (for members of the SMFM Board of Directors, all committee chairs, members of the SMFM COI Committee, SMFM Executive Committee, SMFM Senior Executive Team, and the SMFM CEO), and [Table 3](#) (for SMFM-selected speakers at SMFM-sponsored meetings and presenters at educational sessions at the SMFM Pregnancy Meeting or other scientific meetings).

Any issues pertaining to level C COIs will be confirmed and reviewed by the COI Committee after a referral from a committee chair or SMFM staff liaison. Issues pertaining to level B COIs will be referred to the COI Committee if further assistance is needed for clarity in adjudication. The COI Committee will be available for ongoing assistance if needed in the mitigation plan for the COI. The COI Committee will also become involved in cases of COI referred by means other than the committee chair or SMFM staff liaison. Any additional COI issues beyond those listed herein that require additional assistance can also be referred to the COI Committee.

For SMFM-branded written materials, participants with a level B COI may participate in initial discussions related to a topic and the initial writing process. Thereafter, the member may contribute to ongoing discussions during the editorial process but will not be responsible for further acceptance or denial of edits within the final product. Committee chairs or task force leaders may consider several potential additional actions to resolve relevant nonfinancial COIs with assistance from the COI Committee as needed. These may include participation in topic-related discussions but with restrictions on the writing and editing process or both, or even recusal from participation altogether.

It should be emphasized that the process of nonfinancial COI management is not intended to discourage or preclude subject matter experts from participating in SMFM educational activities and development of SMFM guidelines, policies, and materials. Rather, the goal is to balance the inclusion of recognized expertise, which carries the potential for individual attachment to a specific point of view (even unintended), with a diversity of expertise, thought, and review.

Beyond the process of disclosure and management of COIs, additional actions to be undertaken at the Society level to mitigate the perception of nonfinancial COI when convening a topic- or content-specific activity include the following:

- inclusion of diverse viewpoints in committees, task forces, and other groups and activities
- delineation of the distinct roles of authors, reviewers, committee members, and the internal peer review process used in the development of each guideline and other SMFM-branded recommendations or documents with public availability
- restriction of a lead author of SMFM publications, guidelines, or other formal recommendations from final editing decisions during the formal review process

- use of the existing, formalized, rigorous, internal peer review process of all SMFM-branded documents, publications, and guidelines, which involves review and approval by SMFM Publications, Document Review, and Executive Committees
- inclusion of all participant names who contributed to a publication or formal SMFM document with enumeration of contributing roles
- disclosure of nonfinancial COIs in a link within the publication or guideline; and
- encouraging committee chairs and task force leaders to solicit concerns about nonfinancial COI before convening content-related activity.

The Conflict of Interest Committee

The SMFM COI Committee is a standing committee comprised at least 5 members, including the assistant secretary-treasurer of the SMFM Board of Directors, who serves as a board liaison and who can be recused based on a specific topic, and those initially recommended by the SMFM COI Task Force chair and approved by the Executive Committee of the Board of Directors of SMFM. The members ideally will have rotating 3-year terms, and subsequent membership will be recommended by the COI Committee chair and approved by the SMFM President. COI Committee members (excluding the assistant secretary-treasurer) will not serve concurrently on any other committee, task force, or leadership position within the Society.

The COI Committee will work exclusively with cases referred (level B and C) to the committee by SMFM staff liaisons from each committee, SMFM committee chairs, course directors, the SMFM Pregnancy Meeting program chair, or cases referred publicly to SMFM. SMFM will maintain a webpage with detailed information on the COI policy and also provide a means for verbal, mail, and electronic contact to SMFM for possible inquiries of COI. The COI Committee will report to the Board of Directors and submit an annual report to the board. This report shall be made public but will have the necessary modifications to protect confidential information.

The COI Committee shall:

1. Have no members who themselves have COIs relevant to the activities of SMFM and are in good standing
2. Include at least 1 public member who is not a member of the board or an employee or officer of the Society, and who possesses some relevant expertise
3. Create, as needed, administrative arrangements for the day-to-day oversight and management of institutional COIs, including those involving senior officials. ■

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Please refer to the separate policy on “SMFM Clinical Practice Guidelines Development Process” for details related to the process of guideline and publication development, editing, and review (smfm.org/publications).

Supplemental Material

APPENDIX 1

Development of SMFM clinical guidelines, consult series, and other SMFM-branded statements



COI, conflict of interest; DOI, disclosure of interest; SMFM, Society for Maternal-Fetal Medicine.

SMFM. SMFM special statement: SMFM's conflict of interest policy. *Am J Obstet Gynecol* 2020.

Appendix 2

Conflict of Interest Task Force Members

Brian Iriye, MD (Chair)
 Sean Blackwell, MD
 Michael Foley, MD
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 Mary Norton, MD
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Appendix 3

Specific Financial COI Types

Award: A prize or financial or other symbol of recognition given by a relevant entity.

Board or advisory board membership: Membership on the board of directors or an advisory board of a relevant entity.

Bond: A debt security from a relevant entity in which there is a formal contract to repay borrowed money with interest at fixed intervals.

Carried interest: A distributive share of partnership profits from a relevant entity in excess of the partner's relative capital contribution.

Consulting fee: Payment received from a relevant entity for the provision of personal services, not as an employee, that require advanced knowledge and expertise in a field of science or learning, including the rendering of advice or consultation. It includes fees for services provided as a member of a scientific advisory board or as an agent of a company (eg, someone who receives a commission or finder's fee).

Convertible security: A security that can be converted into a different security, typically shares of a relevant entity's common stock.

Dividend: A portion of a relevant entity's profit that is distributed to shareholders proportionally based on ownership.

Expert witness fee: Payment by a relevant entity for serving as an individual qualified to speak authoritatively by virtue of his or her special education, training, knowledge, skill, or experience/familiarity or payment for providing expert advice related to a scientific, technical, or professional matter. Expert witness services include providing a written report, appearing for a deposition, or otherwise providing information, including testifying under oath on behalf of a relevant healthcare-related entity.

Faculty or speaker fee: Compensation by a relevant entity for speaking to others to impart knowledge or skills in healthcare and life sciences, including, for example, continuing education, board review, seminars, lectures, teaching engagements, or speaker's bureau, or other fees. (Note: The Sunshine Act proposes to define "direct compensation for serving as faculty or as a speaker for a medical education program" as "all instances in which applicable manufacturers pay physicians to serve as speakers, and not just those situations involving medical education programs." As noted, comments were invited in this area and clarification is expected in the final rule. Of note, the proposed rule does not provide guidance about where other faculty fees [such as curriculum development or online courses] should be recorded).

Fiduciary fee: Payment by a relevant entity for serving as a person with the duty to act legally on behalf of that entity, typically ensuring the financial well-being of that entity (eg, as a board member, trustee, governor, manager, executive).

Founder: An individual who has founded or established a relevant entity.

Gifts: A transfer of tangible or intangible value from a relevant entity for which the recipient does not provide equal or greater consideration in return. (Note: Final definitions should follow those in the Sunshine Act final rule [eg, food gifts]).

Grant: A financial transfer of money, property, or both from a relevant entity to perform an approved project or activity.

Honoraria: Payments to a professional person for services by a relevant entity for which fees are not legally or traditionally required (eg, an appearance, speech, article). (Note: the Sunshine Act proposed rule requests comments on the distinction between honoraria and direct compensation for serving as a continuing medical education faculty or speaker. The definition of these 2 items should correspond to the final rule).

License fee: Payment to the holder of a patent or a copyright for a limited right to reproduce, sell, or distribute the patented or copyrighted item by a relevant entity. It includes one-time, scheduled, or milestone payments.

Limited liability company membership: Participation as a stakeholder in a relevant entity that has certain characteristics of both a corporation and a partnership or sole proprietorship.

Loan: The receipt of money or other things of value from a relevant entity, for which a repayment agreement is in place.

Manuscript fee: Compensation received from a relevant entity for authorship, editing, reviewing, or other services associated with the preparation of materials for publication.

Officer fee: Payment for providing executive leadership or management to a relevant entity.

Partnership: A business arrangement in which there are ownership and obligations for a relevant entity as an institution, company, or organization, which are shared among 2 or more individuals.

Patents: Received or pending a government authority or license conferring a right or title for a set period, especially the sole right to exclude others from making, using, or selling an invention.

Review activity fee: Compensation received from a relevant entity for professional review of scientific activities, such as participation on a data-monitoring board, statistical analysis, etc.

Royalty: Compensation from a relevant entity for the use of property, usually copyrighted works, patented inventions, or natural resources, expressed as a percentage of receipts from using the property or as a payment for each unit produced.

Salary: Fixed compensation paid regularly by a relevant entity for services rendered as an employee of a vendor or industry. Disclosure of salary amount for full-time employees is not required.

Stock option: The right to purchase stock of a relevant entity in the future at a price set at the time the option is granted (by sale or as compensation).

Stock: Also known as corporate stock, equity, or equity securities, an instrument (share certificate or stock certificate) that entitles holders (shareholders) to an ownership interest (equity) in a relevant entity and represents a proportional claim on its assets and profits that is individually owned and purchased. Stocks held in blind trusts, mutual funds, or traded funds over which the individual has no control are not included unless these assets are provided to the SMFM participant or family member by the relevant entity.

Other: Any other potential COI type relating to a relevant entity that is not included in this list.