

COI CRITERIA GUIDANCE

A. STOCKS AND INVESTMENTS

In firms expected to be affected by the matters before the Committee; includes SGE's imputed interest* (spouse, minor child and general partner, organization or entity which the employee serves as officer, director, trustee, general partner or employee or with a person with whom the employee is negotiating for or has an arrangement concerning prospective employment)

Involvement Level	Expected Action
Low Involvement	
<p><i>General Matters:</i></p> <ul style="list-style-type: none"> • Stock value is less than or equal to \$25,000 per entity/ \$50,000 in aggregate (5 CFR 2640.202(b) de minimis exemption) 	Cover memo
<p><i>Party Matters:</i></p> <ul style="list-style-type: none"> • Stock value is less than or equal to \$5,000 in aggregate (5 CFR 2640.202(a) de minimis exemption) 	Cover memo
Medium Involvement	
<p><i>General Matters:</i></p> <ul style="list-style-type: none"> • Stock value is greater than \$25,000, but less than or equal to \$100,000 per entity • Stock is 15-25% of SGE's net worth 	Decision (W) Decision (WC)
<p><i>Party Matters:</i></p> <ul style="list-style-type: none"> • Stock value is greater than \$5,000, but less than or equal to \$100,000 per entity (\$50,000 for homework) • Stock is less than 15% of SGE's net worth (less than 5% for homework) 	Decision (WC) Decision (WC)
High Involvement	
<p><i>General Matters:</i></p> <ul style="list-style-type: none"> • Stock value is greater than \$100,000 per entity • Stock value is greater than 25% of SGE's net worth 	

<i>Party Matters:</i> <ul style="list-style-type: none"> • Stock value is greater than \$100,000 for one entity OR greater than 15% of SGE's net worth <p>(For homework: greater than \$50,000 for one entity OR greater than 5% of net worth)</p>	Decision (WC) Decision (WC) Exclusion
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* CDER/CBER see 505 (n)(4) waiver

CIRCUMSTANCES FAVORING USE OF SGE:

- Stock is in parent or subsidiary and not in sponsor or direct competitor
- Product is not a breakthrough or blockbuster product (Division input is required)
- Decision on issue is not likely to cause the stock to rise or fall significantly
- Decision on issue will not affect viability of the company
- Multiple competing products and stock is solely in competitor
- Company involvement is minimal.

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B. PRIMARY EMPLOYMENT

All SGEs (except non-voting industry representatives) including other Federal employees and family members* For consulting activities see Section C.

Involvement Level	Expected Action
Low Involvement	
<i>General Matters:</i> <ul style="list-style-type: none"> • Matters will not have a special or distinct effect on the SGE or employer, the Committee's decision may affect SGE/employer only as a part of a class of product manufacturers (5 CFR 2640.203 (g) exemption for non-Federal employment interests of SGEs on advisory committees) • SGE is a federal employee, and his agency is conducting research for one or more firms with an interest in the general matter before the Committee 	Cover memo Cover memo
<i>Party Matters:</i> <ul style="list-style-type: none"> • The SGE's spouse is employed (stock/stock options or pension plan) in a MEDIUM to LARGE sponsoring or competing firm, but his/her role in the firm is not connected with the product at issue and the employee is not in the management hierarchy. If stock is less than \$5,000 - Cover memo, greater than \$5,000 - Waiver • An individual with whom the SGE has a covered relationship is employed in a MEDIUM to LARGE sponsoring or competing firm, but his/her role in the firm is not connected with the product at issue and the employee is not in the management hierarchy 	Decision (WC) Decision (AC)

Medium Involvement	
<p><i>General Matters:</i></p> <ul style="list-style-type: none"> • Matters will have a special or distinct effect on the SGE or employer <p><i>Party Matters:</i></p> <ul style="list-style-type: none"> • SGE is a federal employee and his agency, not his organizational component, is conducting research on the product under review - funding from the sponsor is less than \$500,000/per year • Within the past 12 months, the SGE was employed by the sponsor or competing firm, but had nothing to do with the issue before the Committee • An individual with whom the SGE has a covered relationship is employed in a MEDIUM to LARGE sponsoring or competing firm and his/her role is/was connected to the product at issue, but is not part of the management hierarchy of the firm AND has financial interest. 	<p>Decision (WC)</p> <p>Cover memo</p> <p>Decision (AE)</p> <p>Decision (AE)</p>
High Involvement	
<p><i>Party Matters:</i></p> <ul style="list-style-type: none"> • SGE is a federal employee and his agency is working on a large collaborative agreement or CRADA in which the sponsor or competitor is providing a large amount (\$500,000) of monetary support. • SGE has a covered (appearance) relationship with individual, e.g., adult child, significant other, who is a party or represents a party to the matter before the Committee • The SGE's spouse is employed in a MEDIUM to LARGE sponsoring or competing firm and his/her role is/was connected to the product at issue, but is not part of the management hierarchy of the firm AND has financial interest • The SGE's spouse is employed by SMALL sponsoring or competing firm, his/her role is irrelevant • The SGE's spouse is an officer in the sponsoring or competing firm, or is the regulatory affairs officer or has significant administrative duties AND/OR has significant financial interests. (Size of the firm is irrelevant) 	<p>Decision (AE)</p> <p>Decision (AE)</p> <p>Decision (WC)</p> <p>Exclusion</p> <p>Exclusion</p>

* CDER/CBER see 505(n)(4) waiver

B. PRIMARY EMPLOYMENT continued

CIRCUMSTANCES FAVORING USE OF SGE:

- Decision would not have a special or distinct effect on the employer
- SGE is not personally involved in CRADA
- CRADA is unrelated to product at issue
- CRADA is not in the same organizational component

- Matter is not sensitive or highly controversial (Division input is required)
- A spouse or person with whom the SGE has a covered relationship has a position with a large firm not directly connected with the product at issue

PROVIDED BELOW IS THE DEFINITION OF COVERED RELATIONSHIP (5 CFR PART 2635.502)

- a person, other than a prospective employer, with whom the SGE has or seeks a business, contractual, or other financial relationship;
- a person who is a member of the SGE's household, or who is a relative with whom the SGE has a close personal relationship;
- a person for whom the SGE's spouse, parent, or dependent child is, to the SGE's knowledge, serving or seeking to serve as an officer, director, trustee, general partner, agent, attorney, consultant, contractor, or employee;
- a person for whom the SGE has served within the last year as officer, director, trustee, general partner, agent, attorney, consultant, contractor, or employee; or
- an organization in which the SGE is an active participant.

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C. CONSULTANT/ADVISOR

With firms expected to be affected by the matter before the Committee* The table refers to current activities unless specified as "past".

Involvement Level	Expected Action
Low Involvement	
<p>SGE receives less than \$10,000 per source per year</p> <p><i>General Matters:</i></p> <ul style="list-style-type: none"> • Consulting on related or unrelated issue completed within the past 12 months (all monies paid) • Consulting on unrelated issue is current or under negotiation • Consulting on related issue is current or under negotiation <p><i>Party Matters:</i></p> <ul style="list-style-type: none"> • Consulting on unrelated issue in the past or completed within the past 12 months (all monies paid) • Consulting on unrelated issue is current or under negotiation • Consulting on related issue in the past • Consulting on related issue is current or under negotiation 	<p>Cover memo Decision (W) Decision (WC)</p> <p>Cover memo Decision (W) Decision (AC) Exclusion</p>
Medium Involvement	
<p>SGE receives between \$10,000 and \$50,000 per source per year</p>	

<p><i>General Matters:</i></p> <ul style="list-style-type: none"> • Consulting on related or unrelated issue completed within the past 12 months (all monies paid) • Consulting on unrelated issue is current or under negotiation • Consulting on related issue is current or under negotiation <p><i>Party Matters:</i></p> <ul style="list-style-type: none"> • Consulting on unrelated issue in the past or completed within the past 12 months (all monies paid) • Consulting on related issue in the past or completed within the past 12 months (all monies paid) • Consulting is general in nature and does not involve product development or research • Consulting is for a competitor's related issue, but SGE does not hold a prominent role • Consulting is current or under negotiation for product or related products 	<p>Cover memo Decision (W) Decision (WG)</p> <p>Cover memo Decision (AC) Decision (W) Decision (WG) Exclusion</p>
High Involvement	
SGE receives more than \$50,000 per source per year	
<p><i>General Matters:</i></p> <ul style="list-style-type: none"> • Consulting on related or unrelated issue completed within the past 12 months (all monies paid) • Consulting on unrelated issue is current or under negotiation • Consulting on related issue is current or under negotiation <p><i>Party Matters:</i></p> <ul style="list-style-type: none"> • Consulting on sponsor's or competitor's unrelated product • Consulting on sponsor's or competitor's product 	<p>Cover memo Decision (W) Decision (WG)</p> <p>Exclusion ** Exclusion</p>

* CDER/CBER see 505(n)(4) waiver

**SGE may be granted a limited waiver in cases where the expertise is otherwise not available

C. CONSULTANT/ADVISOR continued

CIRCUMSTANCES FAVORING USE OF SGE:

- SGE was involved only in early stage of product development
- SGE's compensation is at the low end of the cited range
- SGE has no ongoing involvement with the sponsor/competitors
- SGE will provide expertise that is otherwise not available to the committee
- Product matter is not controversial or highly sensitive (Division input is required)
- Decisions are not likely to have an effect on the continuing relationship between SGE

and the firm

- Decision on product is not expected to affect viability of the company
- Product is studied widely; therefore, it would be difficult to find a qualified SGE who is not equally involved
- There are more than five competing products on the market
- All monies have been paid

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D. CONTRACTS/GRANTS/GRADAS (DEPARTMENT CHAIR - SEE SECTION H

Involving SGE's University/Hospital/Employer and firms expected to be affected by the matter before the Committee*

The table refers to current activities unless specified as "past."

Involvement Level	Expected Action
Low Involvement	
<p>Remuneration is less than \$100,000 per source per year to institution /\$10,000 per source per year as salary support to the SGE</p> <p><i>General Matters:</i></p> <ul style="list-style-type: none"> • Work on unrelated matter is current or completed within the past 12 months • Work on related matter has been completed over a year ago • Work on related matter <p><i>Party Matters:</i></p> <ul style="list-style-type: none"> • Work on unrelated product is currently active or completed within the past 12 months • Work is general on related product or SGE will be the principal investigator (PI) on competitor's product • SGE is or will be the principal investigator (PI) on sponsor's product 	<p>Cover memo Cover memo Decision (W)</p> <p>Cover memo Decision (WC) Exclusion**</p>
Medium Involvement	
<p>Remuneration is between \$100,000-\$300,000 per source/year to institution/\$10,000-\$15,000 per source/year as salary support to the SGE</p> <p><i>General Matters:</i></p> <ul style="list-style-type: none"> • Work on unrelated matter is current or completed within past 12 months • Work on related matter <p><i>Party Matters:</i></p>	<p>Cover memo Decision (WC)</p>

<ul style="list-style-type: none"> • Work on unrelated product is current or completed within past 12 months • SGE has a limited role in work on product or competing product • Work was on competitor's product with SGE as PI, but completed more than a year ago • SGE is or will be PI on sponsor's or competitor's product 	Decision (AE) Decision (WC) Decision (AC) Exclusion**
High Involvement	
Remuneration is more than \$300,000 per source/year to institution//\$15,000 per source/year as salary support to the SGE	
<i>General Matters:</i>	
<ul style="list-style-type: none"> • Work on unrelated product is current or completed within past 12 months • Work on related matter 	Decision (AE) Decision (WC)
<i>Party Matters:</i>	
<ul style="list-style-type: none"> • Work on unrelated product • SGE is PI on sponsor's product 	Decision (AE) Exclusion**

*CDER/CBER see 505(n)(4) waiver

** See next page

D. CONTRACTS/GRANTS/CRADAS continued

CIRCUMSTANCES FAVORING USE OF SGE:

- Decision is not likely to affect continuing relationship between SGE and sponsors/competitors
- Decision is not likely to affect the stability of companies involved
- Funding is from another government agency, rather than the manufacturer
- All payments have been made and a final report published
- Study has multiple sites
- SGE is not grant manager
- There are more than five competing products on the market
- SGE not involved in grant at all

EXCLUSION CRITERIA FOR INVESTIGATORS:

- Any individual who has contributed patient data to the application at issue before the Committee
- Any individual who has contributed patient data to a directly competing (breakthrough) product to the application at issue before the Committee
- Notable exceptions to the above:
 - a. Any individual who has contributed patient data to an expanded access or compassionate use trial
 - b. Any individual who has provided laboratory findings to support the diagnostic definitions and who does not receive salary support
 - c. Any individual previously involved with an approved product if the issue before

the Committee is a new indication for the product

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E: PATENTS/ROYALTIES/TRADEMARKS

Since a patent is an intellectual property interest and a potential source of income, it may be considered a financial interest even if no licensing of the patent has occurred.

Involvement Level	Expected Action
Low Involvement	
<p>SGE receives less than \$15,000 in royalties per affected source annually</p> <p><i>General Matters:</i></p> <ul style="list-style-type: none"> • SGE has a patent that has been in existence for a long time but no licensing or potential commercial use is envisioned • SGE has a patent with relevance to general matters and receives or anticipates royalties <p><i>Party Matters:</i></p> <ul style="list-style-type: none"> • SGE has a patent on an unrelated product, licensed by a competing firm, and receives royalties • SGE has a patent that could be used in products that would compete with the product at issue, but no firm has licensed it yet 	<p>Decision (W)</p> <p>Decision (W)</p> <p>Cover memo Decision (W)</p>
Medium Involvement	
<p>SGE receives between \$15,000 - 100,000 in royalties per affected source annually</p> <p><i>General and Party Matters:</i></p> <ul style="list-style-type: none"> • SGE has a patent on an unrelated product, and receives royalties from a firm at issue • SGE has a patent on the product at issue or a competing product 	<p>Decision (AE)</p> <p>Exclusion</p>
High Involvement	
<p>SGE receives more than \$100,000 in royalties per affected source annually</p> <p><i>General Matters:</i></p> <ul style="list-style-type: none"> • SGE has a patent on an unrelated product and receives royalties from a firm at issue <p><i>Party Matters:</i></p>	<p>Decision (AE)</p>

<ul style="list-style-type: none"> • SGE has a patent on an unrelated product and receives royalties from the sponsor or competing firms • SGE has a patent on the product at issue or a competing product 	Exclusion Exclusion
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CIRCUMSTANCES FAVORING USE OF SGE:

- Royalties received are in low involvement range
- Decision would have little impact, either negative or positive, on the value of the patent or ability of licensee to pay royalties
- There are many competing products on the market, so less likelihood that value of patent or competing product would be affected
- There is no past history or pending patent litigation between SGE and sponsor
- For example, an SGE would not have a 208 issue usually if participating in matter affecting the sponsor who pays the royalties, unless the matter affects the particular product (maybe a 502 covered relationship)
- If the matter could affect the company's ability to pay royalties on an unrelated patent, it could be a 208 issue

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F. EXPERT WITNESS

NOTE: Apart from the considerations below, SGEs are subject to the following restriction on their expert witness activities: They may not serve as an expert witness in any proceeding of a federal court or agency, if they have participated in the same proceeding or particular matter that is the subject of the proceeding or particular matter as part of their official duties and if the U.S. is a party or has a direct and substantial interest. Additional restrictions, usually not applicable to FDA advisory committee members, apply to certain SGEs 5 C.F.R. section 2635.805.

Involvement Level	Expected Action
Low Involvement	
Remuneration is less than \$5,000 per affected source per year <i>General:</i> <ul style="list-style-type: none"> • SGE makes no statement for or against any product of a sponsor or competitor <i>Party Matters:</i> <ul style="list-style-type: none"> • SGE makes no statement for or against any product of a sponsor or competitor 	Cover memo Decision (AC)
Medium Involvement	
Remuneration is between \$5,000 and \$10,000 per affected source per year	