

ICMJE Form for Disclosure of Potential Conflicts of Interest

Instructions

The purpose of this form is to provide readers of your manuscript with information about your other interests that could influence how they receive and understand your work. The form is designed to be completed electronically and stored electronically. It contains programming that allows appropriate data display. Each author should submit a separate form and is responsible for the accuracy and completeness of the submitted information. The form is in four parts.

1. Identifying information.

Enter your full name. If you are NOT the corresponding author please check the box "no" and a space to enter the name of the corresponding author in the space that appears. Provide the requested manuscript information. Double-check the manuscript number and enter it.

2. The work under consideration for publication.

This section asks for information about the work that you have submitted for publication. The time frame for this reporting is that of the work itself, from the initial conception and planning to the present. The requested information is about resources that you received, either directly or indirectly (via your institution), to enable you to complete the work. Checking "No" means that you did the work without receiving any financial support from any third party -- that is, the work was supported by funds from the same institution that pays your salary and that institution did not receive third-party funds with which to pay you. If you or your institution received funds from a third party to support the work, such as a government granting agency, charitable foundation or commercial sponsor, check "Yes". Then complete the appropriate boxes to indicate the type of support and whether the payment went to you, or to your institution, or both.

3. Relevant financial activities outside the submitted work.

This section asks about your financial relationships with entities in the bio-medical arena that could be perceived to influence, or that give the appearance of potentially influencing, what you wrote in the submitted work. You should disclose interactions with ANY entity that could be considered broadly relevant to the work. For example, if your article is about testing an epidermal growth factor receptor (EGFR) antagonist in lung cancer, you should report all associations with entities pursuing diagnostic or therapeutic strategies in cancer in general, not just in the area of EGFR or lung cancer.

Report all sources of revenue paid (or promised to be paid) directly to you or your institution on your behalf over the 36 months prior to submission of the work. This should include all monies from sources with relevance to the submitted work, not just monies from the entity that sponsored the research. Please note that your interactions with the work's sponsor that are outside the submitted work should also be listed here. If there is any question, it is usually better to disclose a relationship than not to do so.

For grants you have received for work outside the submitted work, you should disclose support ONLY from entities that could be perceived to be affected financially by the published work, such as drug companies, or foundations supported by entities that could be perceived to have a financial stake in the outcome. Public funding sources, such as government agencies, charitable foundations or academic institutions, need not be disclosed. For example, if a government agency sponsored a study in which you have been involved and drugs were provided by a pharmaceutical company, you need only list the pharmaceutical company.

4. Other relationships.

Use this section to report other relationships or activities that readers could perceive to have influenced, or that give the appearance of potentially influencing, what you wrote in the submitted work.

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Section 1. Identifying Information

1. Given Name (First Name) Aaron	2. Surname (Last Name) Kesselheim	3. Effective Date (07-August-2008) 17-March-2011
4. Are you the corresponding author? <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No		Corresponding Author's Name Jerry Avorn
5. Manuscript Title A Hemorrhage of Off-Label Use		
6. Manuscript Identifying Number (if you know it) M11-0550		

Section 2. The Work Under Consideration for Publication

Did you or your institution at any time receive payment or services from a third party for any aspect of the submitted work (including but not limited to grants, data monitoring board, study design, manuscript preparation, statistical analysis, etc...)?

Complete each row by checking "No" or providing the requested information. If you have more than one relationship click the "Add" button to add a row. Excess rows can be removed by clicking the "X" button.

The Work Under Consideration for Publication						
Type	No	Money Paid to You	Money to Your Institution*	Name of Entity	Comments**	
1. Grant	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	AHRQ	Dr. Kesselheim is supported by a career development award from the Agency for Healthcare Research and Quality (K08HS18465-01).	X
1. Grant	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	Robert Wood Johnson Foundation	Dr. Kesselheim is supported by a Robert Wood Johnson Foundation Investigator Award in Health Policy Research.	X
						ADD
2. Consulting fee or honorarium	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>			X
						ADD
3. Support for travel to meetings for the study or other purposes	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>			X
						ADD

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The Work Under Consideration for Publication						
Type	No	Money Paid to You	Money to Your Institution*	Name of Entity	Comments**	
4. Fees for participation in review activities such as data monitoring boards, statistical analysis, end point committees, and the like	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>			X
						ADD
5. Payment for writing or reviewing the manuscript	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>			X
						ADD
6. Provision of writing assistance, medicines, equipment, or administrative support	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>			X
						ADD
7. Other	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>			X
						ADD

* This means money that your institution received for your efforts on this study.

** Use this section to provide any needed explanation.

Section 3.

Relevant financial activities outside the submitted work.

Place a check in the appropriate boxes in the table to indicate whether you have financial relationships (regardless of amount of compensation) with entities as described in the instructions. Use one line for each entity; add as many lines as you need by clicking the "Add +" box. You should report relationships that were present during the 36 months prior to submission.

Complete each row by checking "No" or providing the requested information. If you have more than one relationship click the "Add" button to add a row. Excess rows can be removed by clicking the "X" button.

Relevant financial activities outside the submitted work						
Type of Relationship (in alphabetical order)	No	Money Paid to You	Money to Your Institution*	Entity	Comments	
1. Board membership	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>			X
						ADD
2. Consultancy	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>			X
						ADD
3. Employment	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>			X
						ADD

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Type of Relationship (in alphabetical order)	No	Money Paid to You	Money to Your Institution*	Entity	Comments	
4. Expert testimony	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	Texas	From 2008-2009, Dr. Kesselheim served as an expert witness for the state of Texas in a lawsuit against Merck related to improper promotion of rofecoxib (Vioxx).	×
						ADD
5. Grants/grants pending	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	Attorney General Prescriber and Consumer Education Grant Program	From 2007-2009, Dr. Kesselheim was the project manager on a grant ("Educational outreach to improve prescribing practices") funded by a portion of the settlement from the gabapentin off-label use investigation.	×
						ADD
6. Payment for lectures including service on speakers bureaus	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>			×
						ADD
7. Payment for manuscript preparation	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>			×
						ADD
8. Patents (planned, pending or issued)	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>			×
						ADD
9. Royalties	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>			×
						ADD
10. Payment for development of educational presentations	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>			×
						ADD
11. Stock/stock options	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>			×
						ADD
12. Travel/accommodations/meeting expenses unrelated to activities listed**	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>			×
						ADD

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13. Other (err on the side of full disclosure)	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>			X
						ADD

* This means money that your institution received for your efforts.

** For example, if you report a consultancy above there is no need to report travel related to that consultancy on this line.

Section 4.

Other relationships

Are there other relationships or activities that readers could perceive to have influenced, or that give the appearance of potentially influencing, what you wrote in the submitted work?

- ☒ No other relationships/conditions/circumstances that present a potential conflict of interest
- ☐ Yes, the following relationships/conditions/circumstances are present (explain below):

At the time of manuscript acceptance, journals will ask authors to confirm and, if necessary, update their disclosure statements. On occasion, journals may ask authors to disclose further information about reported relationships.

Hide All Table Rows Checked 'No'

SAVE

Evaluation and Feedback

Please visit <http://www.icmje.org/cgi-bin/feedback> to provide feedback on your experience with completing this form.

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4. Expert testimony	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>			X
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9. Royalties	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>			×
						ADD
10. Payment for development of educational presentations	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>			×
						ADD
11. Stock/stock options	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>			×
						ADD
12. Travel/accommodations/meeting expenses unrelated to activities listed**	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>			×
						ADD
13. Other (err on the side of full disclosure)	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		In the coming year I expect to provide pro bono consultation to an independent epidemiology research company on patterns of treatment for patients with hemophilia. That company will receive support from Baxter; I will receive no compensation for my efforts.	×
						ADD

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