

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 six parts.

1. Identifying information.

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".

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4. Intellectual Property.

This section asks about patents and copyrights, whether pending, issued, licensed and/or receiving royalties.

5. Relationships not covered above.

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Entity: government agency, foundation, commercial sponsor, academic institution, etc.

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Personal Fees: Monies paid to you for services rendered, generally honoraria, royalties, or fees for consulting, lectures, speakers bureaus, expert testimony, employment, or other affiliations

Non-Financial Support: Examples include drugs/equipment supplied by the entity, travel paid by the entity, writing assistance, administrative support, etc.

Other: Anything not covered under the previous three boxes

Pending: The patent has been filed but not issued

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Licensed: The patent has been licensed to an entity, whether earning royalties or not

Royalties: Funds are coming in to you or your institution due to your patent

ICMJE Form for Disclosure of Potential Conflicts of Interest

Section 1. Identifying Information

1. Given Name (First Name) Sanket	2. Surname (Last Name) Dhruva	3. Date 21-March-2018
4. Are you the corresponding author? <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No		Corresponding Author's Name Joshua D Wallach, PhD
5. Manuscript Title Postmarket studies required by the US Food and Drug Administration for new drugs and biologics approved between 2009 and 2012: cross-sectional evaluation		
6. Manuscript Identifying Number (if you know it) BMJ.2018.043625		

Section 2. The Work Under Consideration for Publication

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

Are there any relevant conflicts of interest? ☐ Yes ☒ No

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 publication**.

Are there any relevant conflicts of interest? ☒ Yes ☐ No

If yes, please fill out the appropriate information below.

Name of Entity	Grant?	Personal Fees?	Non-Financial Support?	Other?	Comments
Food & Drug Administration, Center for Drug Evaluation and Research	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	Reimbursement for travel only

Section 4. Intellectual Property -- Patents & Copyrights

Do you have any patents, whether planned, pending or issued, broadly relevant to the work? ☐ Yes ☒ No

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Section 5. Relationships not covered above

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Dr. Dhruva reports other from Food & Drug Administration, Center for Drug Evaluation and Research, outside the submitted work; .

Evaluation and Feedback

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ICMJE Form for Disclosure of Potential Conflicts of Interest

Section 1. Identifying Information

1. Given Name (First Name) Alexander	2. Surname (Last Name) Egilman	3. Date 20-March-2018
4. Are you the corresponding author? <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No		Corresponding Author's Name Joshua D Wallach, PhD
5. Manuscript Title Postmarket studies required by the US Food and Drug Administration for new drugs and biologics approved between 2009 and 2012: cross-sectional evaluation		
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Section 2. The Work Under Consideration for Publication

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

Are there any relevant conflicts of interest? ☒ Yes ☐ No

If yes, please fill out the appropriate information below. If you have more than one entity press the "ADD" button to add a row. Excess rows can be removed by pressing the "X" button.

Name of Institution/Company	Grant?	Personal Fees?	Non-Financial Support?	Other?	Comments
Laura and John Arnold Foundation	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	This project was conducted as part of the Collaboration for Research Integrity and Transparency (CRIT) at Yale, funded by the Laura and John Arnold Foundation, which supports Mr. Egilman and Drs. McCarthy, Wallach, and Ross.

Section 3. Relevant financial activities outside the submitted work.

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Are there any relevant conflicts of interest? ☐ Yes ☒ No

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Section 4. Intellectual Property -- Patents & Copyrights

Do you have any patents, whether planned, pending or issued, broadly relevant to the work? ☐ Yes ☒ No

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Mr. Egilman reports grants from Laura and John Arnold Foundation, during the conduct of the study.

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ICMJE Form for Disclosure of Potential Conflicts of Interest

Section 1. Identifying Information

1. Given Name (First Name) Margaret E.	2. Surname (Last Name) McCarthy	3. Date 26-March-2018
4. Are you the corresponding author? <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No		Corresponding Author's Name Joshua D Wallach, PhD
5. Manuscript Title Postmarket studies required by the US Food and Drug Administration for new drugs and biologics approved between 2009 and 2012: cross-sectional evaluation		
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Are there any relevant conflicts of interest? ☒ Yes ☐ No

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Name of Institution/Company	Grant?	Personal Fees?	Non-Financial Support?	Other?	Comments
Laura and John Arnold Foundation	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	grant to the Collaboration for Research Integrity and Transparency, Yale University

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Section 4. Intellectual Property -- Patents & Copyrights

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Dr. McCarthy reports grants from Laura and John Arnold Foundation, during the conduct of the study; .

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ICMJE Form for Disclosure of Potential Conflicts of Interest

Section 1. Identifying Information

1. Given Name (First Name) Jennifer	2. Surname (Last Name) Miller	3. Date 27-March-2018
4. Are you the corresponding author? <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No		Corresponding Author's Name Joshua D Wallach, PhD
5. Manuscript Title Postmarket studies required by the US Food and Drug Administration for new drugs and biologics approved between 2009 and 2012: cross-sectional evaluation		
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Are there any relevant conflicts of interest? ☒ Yes ☐ No

If yes, please fill out the appropriate information below. If you have more than one entity press the "ADD" button to add a row. Excess rows can be removed by pressing the "X" button.

Name of Institution/Company	Grant?	Personal Fees?	Non-Financial Support?	Other?	Comments
The Laura and John Arnold Foundation	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Dr. Miller received a grant from The Laura and John Arnold Foundation, through Bioethics International for the Good Pharma Scorecard and to address integrity and transparency issues in the pharmaceutical industry.

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Section 1. Identifying Information

1. Given Name (First Name) Joseph	2. Surname (Last Name) Ross	3. Date 26-March-2018
4. Are you the corresponding author? <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No		Corresponding Author's Name Joshua D Wallach, PhD
5. Manuscript Title Postmarket studies required by the US Food and Drug Administration for new drugs and biologics approved between 2009 and 2012: cross-sectional evaluation		
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Are there any relevant conflicts of interest? ☒ Yes ☐ No

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Name of Entity	Grant?	Personal Fees?	Non-Financial Support?	Other?	Comments
Food and Drug Administration (FDA)	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Dr. Ross receives support from the Food and Drug Administration (FDA) through a research grant to determine best practices in medical device post-market surveillance.
Medtronic, Inc.	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Dr. Ross receives support from Medtronic, Inc. through a research grant to determine best practices in medical device post-market surveillance.
Johnson & Johnson	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Dr. Ross receives support from Johnson & Johnson through the Yale University Open Access Data project to develop methods to promote clinical trial data sharing.
Centers for Medicare and Medicaid Services (CMS)	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Dr. Ross receives support through a contract with the Centers for Medicare and Medicaid Services (CMS) to develop and maintain performance measures that are used to publicly report hospital and physician quality of care.
Blue Cross-Blue Shield Association (BCBSA)	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Dr. Ross received support from the Blue Cross-Blue Shield Association (BCBSA) through a research grant to better understand medical technology evidence generation.
Food and Drug Administration (FDA)	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Dr. Ross receives support from the Food and Drug Administration (FDA) through a research grant to establish the Yale-Mayo Clinic Center for Excellence in Regulatory Science and Innovation (CERSI).
Agency for Healthcare Research and Quality (AHRQ)	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Dr. Ross receives support from the Agency for Healthcare Research and Quality (AHRQ) through a research grant to study patient, hospital and community factors associated with readmission risk.
Laura and John Arnold Foundation	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Dr. Ross receives support from the Laura and John Arnold Foundation through a research grant to support the Good Pharma Scorecard.
National Institutes of Health (NIH/NHLBI)	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Dr. Ross receives support from the National Institutes of Health (NIH/ NHLBI) through a research grant to study the diffusion of clinical evidence into practice.

ICMJE Form for Disclosure of Potential Conflicts of Interest

Section 4. Intellectual Property -- Patents & Copyrights

Do you have any patents, whether planned, pending or issued, broadly relevant to the work? ☐ Yes ☒ No

Section 5. Relationships not covered above

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?

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

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Dr. Ross reports grants from The Laura and John Arnold Foundation, during the conduct of the study; grants from Food and Drug Administration (FDA), grants from Medtronic, Inc., grants from Johnson & Johnson, grants from Centers for Medicare and Medicaid Services (CMS), grants from Blue Cross-Blue Shield Association (BCBSA), grants from Food and Drug Administration (FDA), grants from Agency for Healthcare Research and Quality (AHRQ), grants from Laura and John Arnold Foundation, grants from National Institutes of Health (NIH/NHLBI), outside the submitted work; .

Evaluation and Feedback

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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. Intellectual Property.

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5. Relationships not covered above.

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Personal Fees: Monies paid to you for services rendered, generally honoraria, royalties, or fees for consulting, lectures, speakers bureaus, expert testimony, employment, or other affiliations

Non-Financial Support: Examples include drugs/equipment supplied by the entity, travel paid by the entity, writing assistance, administrative support, etc.

Other: Anything not covered under the previous three boxes

Pending: The patent has been filed but not issued

Issued: The patent has been issued by the agency

Licensed: The patent has been licensed to an entity, whether earning royalties or not

Royalties: Funds are coming in to you or your institution due to your patent

ICMJE Form for Disclosure of Potential Conflicts of Interest

Section 1. Identifying Information

1. Given Name (First Name) Lisa	2. Surname (Last Name) Schwartz	3. Date 19-March-2018
4. Are you the corresponding author? <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No		Corresponding Author's Name Joshua D Wallach, PhD
5. Manuscript Title Postmarket studies required by the US Food and Drug Administration for new drugs and biologics approved between 2009 and 2012: cross-sectional evaluation		
6. Manuscript Identifying Number (if you know it) BMJ.2018.043625		

Section 2. The Work Under Consideration for Publication

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

Are there any relevant conflicts of interest? ☐ Yes ☒ No

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 publication**.

Are there any relevant conflicts of interest? ☒ Yes ☐ No

If yes, please fill out the appropriate information below.

Name of Entity	Grant?	Personal Fees?	Non-Financial Support?	Other?	Comments
Informulary, Inc.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	Co-founder, ceased operations in December 2016
Cassey Fellers	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	Medical expert in testosterone litigation

Section 4. Intellectual Property -- Patents & Copyrights

Do you have any patents, whether planned, pending or issued, broadly relevant to the work? ☐ Yes ☐ No

ICMJE Form for Disclosure of Potential Conflicts of Interest

Section 5. Relationships not covered above

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Dr. Schwartz has served as medical experts in testosterone litigation and was the cofounder of Informulary, Inc., a company that provided data about the benefits and harms of prescription drugs, which ceased operations in December 2016.

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4. Intellectual Property.

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ICMJE Form for Disclosure of Potential Conflicts of Interest

Section 1. Identifying Information

1. Given Name (First Name) Joshua	2. Surname (Last Name) Wallach	3. Date 27-March-2018
4. Are you the corresponding author? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No		
5. Manuscript Title Postmarket studies required by the US Food and Drug Administration for new drugs and biologics approved between 2009 and 2012: cross-sectional evaluation		
6. Manuscript Identifying Number (if you know it) BMJ.2018.043625		

Section 2. The Work Under Consideration for Publication

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

Are there any relevant conflicts of interest? ☒ Yes ☐ No

If yes, please fill out the appropriate information below. If you have more than one entity press the "ADD" button to add a row. Excess rows can be removed by pressing the "X" button.

Name of Institution/Company	Grant?	Personal Fees?	Non-Financial Support?	Other?	Comments
The Laura and John Arnold Foundation	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	This project was supported by a grant from the Laura and John Arnold Foundation to support the Collaboration for Research Integrity and Transparency (CRIT) at Yale.

Section 3. Relevant financial activities outside the submitted work.

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Are there any relevant conflicts of interest? ☒ Yes ☐ No

If yes, please fill out the appropriate information below.

ICMJE Form for Disclosure of Potential Conflicts of Interest

Name of Entity	Grant?	Personal Fees?	Non-Financial Support?	Other?	Comments
The Laura and John Arnold Foundation	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Dr. Wallach received research support through the Meta Research Innovation Center at Stanford (METRICS) from the Laura and John Arnold Foundation

Section 4. Intellectual Property -- Patents & Copyrights

Do you have any patents, whether planned, pending or issued, broadly relevant to the work? ☐ Yes ☒ No

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ICMJE Form for Disclosure of Potential Conflicts of Interest

Section 1. Identifying Information

1. Given Name (First Name) Steven	2. Surname (Last Name) Woloshin	3. Date 19-March-2018
4. Are you the corresponding author? <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No		Corresponding Author's Name Joshua D Wallach, PhD
5. Manuscript Title Postmarket studies required by the US Food and Drug Administration for new drugs and biologics approved between 2009 and 2012: cross-sectional evaluation		
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If yes, please fill out the appropriate information below.

Name of Entity	Grant?	Personal Fees?	Non-Financial Support?	Other?	Comments
Ross, Feller, Casey (law firm)	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Medical experts in testosterone litigation (against testosterone manufacturers)
Informulary, Inc.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	Co-founder of Informulary, a company which summarized drug evidence. The company ceased operations in December 2016

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