

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".

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.

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

5. Relationships not covered above.

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Definitions.

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Other: Anything not covered under the previous three boxes

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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)

Nilay

2. Surname (Last Name)

Shah

3. Date

09-April-2019

4. Are you the corresponding author?

☐ Yes

☒ No

Corresponding Author's Name

Ali Duarte-Garcia

5. Manuscript Title

Older drugs with limited trial evidence - are they worth the expense? The case of H.P. Acthar gel

6. Manuscript Identifying Number (if you know it)

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

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- ☒ Yes, the following relationships/conditions/circumstances are present (explain below):
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In the past 36-months, Dr. Shah has received research support through Mayo Clinic from the Food and Drug Administration to establish Yale-Mayo Clinic Center for Excellence in Regulatory Science and Innovation (CERSI) program (U01FD005938), from the Centers of Medicare and Medicaid Innovation under the Transforming Clinical Practice Initiative (TCPI), from the Agency for Healthcare Research and Quality (R01HS025164; R01HS025402; 1U19HS024075; R03HS025517), from the National Heart, Lung and Blood Institute of the National Institutes of Health (NIH) (R56HL130496; R01HL131535), National Science Foundation, and from the Patient-Centered Outcomes Research Institute (PCORI) to develop a Clinical Data Research Network (LHSNet).

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Section 6. Disclosure Statement

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Dr. Shah reports receiving research support through Mayo Clinic from the Food and Drug Administration to establish Yale-Mayo Clinic Center for Excellence in Regulatory Science and Innovation (CERSI) program (U01FD005938), from the Centers of Medicare and Medicaid Innovation under the Transforming Clinical Practice Initiative (TCPI), from the Agency for Healthcare Research and Quality (R01HS025164; R01HS025402; 1U19HS024075; R03HS025517), from the National Heart, Lung and Blood Institute of the National Institutes of Health (NIH) (R56HL130496; R01HL131535), National Science Foundation, and from the Patient-Centered Outcomes Research Institute (PCORI) to develop a Clinical Data Research Network (LHSNet)..

Evaluation and Feedback

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Section 1. Identifying Information

1. Given Name (First Name)
Ali

2. Surname (Last Name)
Duarte Garcia

3. Date
26-March-2019

4. Are you the corresponding author? ☒ Yes ☐ No

5. Manuscript Title
Older drugs with limited trial evidence ? are they worth the expense? The case of H.P. Acthar gel

6. Manuscript Identifying Number (if you know it)
M18-3513

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Section 1. Identifying Information

1. Given Name (First Name) Eric	2. Surname (Last Name) Matteson	3. Date 31-January-2019
4. Are you the corresponding author? <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No		Corresponding Author's Name Ali Duarte-Garcia
5. Manuscript Title Ghosts of drugs past: The Case of Acthar gel		
6. Manuscript Identifying Number (if you know it) M18-3513		

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If yes, please fill out the appropriate information below.

Name of Entity	Grant?	Personal Fees?	Non-Financial Support?	Other?	Comments
Pfizer, Amgen, Celgene,	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Janssen, Regeron	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Novartis	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Sun Pharmaceuticals	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Genentech/ Roche	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Advisory board
Boehringer-Ingelheim	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	

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Dr. Matteson reports grants from Pfizer, Amgen, Celgene, , grants from Janssen, Regeneron, grants from Novartis, grants from Sun Pharmaceuticals, grants from Genentech/ Roche, personal fees from Boehringer-Ingelheim, outside the submitted work; .

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