ICMJE Form for Disclosure of Potential Conflicts of Interest

Instructions

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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) Andrew
2. Surname (Last Name) Spitzer
3. Date 29-January-2017
4. Are you the corresponding author? ☑ Yes
5. Manuscript Title
   Effects of a Single Intra-Articular Injection of a Microsphere-Formulation of Triamcinolone Acetonide on Knee Osteoarthritis Pain: A double-blind, randomized, placebo-controlled, multinational study
6. Manuscript Identifying Number (if you know it)

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Are there any relevant conflicts of interest? ☑ Yes

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If yes, please fill out the appropriate information below.

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<thead>
<tr>
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<th>Non-Financial Support?</th>
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<td>Consulting and Research Support</td>
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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
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Dr. Spitzer reports personal fees from Flexion Therapeutics, personal fees from Sanofi Biosurgical, personal fees from DePuy, outside the submitted work.

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<tr>
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<tr>
<td>Diane Jane</td>
<td>Burgess</td>
<td>13-December-2016</td>
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<th>4. Are you the corresponding author?</th>
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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  

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.

<table>
<thead>
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<td>University of Connecticut</td>
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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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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?

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Section 6. Disclosure Statement

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Dr. Burgess reports grants from University of Connecticut, during the conduct of the study.

Evaluation and Feedback

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Section 1. Identifying Information

1. Given Name (First Name)  
   David

2. Surname (Last Name)  
   Hunter

3. Date  
   08-December-2016

4. Are you the corresponding author?  
   Yes  Yes

   Corresponding Author’s Name  
   Philip Conaghan

5. Manuscript Title  
   Effects of a single intra-articular injection of a microsphere-formulation of triamcinolone acetonide on knee osteoarthritis pain. A double-blind, randomized, placebo-controlled, multinational study

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<th>Non-Financial Support?</th>
<th>Other?</th>
<th>Comments</th>
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<tr>
<td>Consultant for Merck Serono and Flexion</td>
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<td>Yes</td>
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Do you have any patents, whether planned, pending or issued, broadly relevant to the work?  
Yes  Yes

Yes  Yes

No  ✕
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Dr. Hunter reports personal fees from Consultant for Merck Serono and Flexion, outside the submitted work.

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Section 1. Identifying Information

1. Given Name (First Name)  
   David

2. Surname (Last Name)  
   Jevsevar

3. Date  
   20-April-2017

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

Corresponding Author’s Name  
Philip Conaghan

5. Manuscript Title  
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Board of Directors, American Academy of Orthopaedic Surgeons

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Dr. Jevsevar reports and Board of Directors, American Academy of Orthopaedic Surgeons.

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Deryk

2. Surname (Last Name)  
Jones

3. Date  
19-December-2016

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☐ Yes  ☑ No

Corresponding Author’s Name  
Philip G. Conaghan

5. Manuscript Title  
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If yes, please fill out the appropriate information below.

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<th>Name of Entity</th>
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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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Section 6. Disclosure Statement

Based on the above disclosures, this form will automatically generate a disclosure statement, which will appear in the box below.

Dr. Jones reports grants from Flexion, other from Sanofi, other from Samumed (all <$10,000), other from Depuy Mitek (> $10,000), outside the submitted work.

Evaluation and Feedback

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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)                      2. Surname (Last Name)                      3. Date
Francis                                                    Berenbaum                                           21-April-2017

4. Are you the corresponding author?  Yes ☑ No

Corresponding Author’s Name
Philip CONAGHAN

5. Manuscript Title
Effects of a Single Intra-Articular Injection of a Microsphere-Formulation of Triamcinolone Acetonide on Knee Osteoarthritis Pain. A double-blind, randomized, placebo-controlled, multinational study

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Are there any relevant conflicts of interest?  Yes ☑ No

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Are there any relevant conflicts of interest?  Yes ☑ No

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### ICMJE Form for Disclosure of Potential Conflicts of Interest

**Name of Entity** | **Grant?** | **Personal Fees?** | **Non-Financial Support?** | **Other?** | **Comments**
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MerckSerono |  | ✔️ |  |  |  |
Servier | ✔️ | ✔️ |  |  |  |
Expanscience |  | ✔️ |  |  |  |
Sanofi |  | ✔️ |  |  |  |
UCB |  | ✔️ |  |  |  |
Novartis |  | ✔️ |  |  |  |
Biogaran |  | ✔️ |  |  |  |
Biogen |  | ✔️ |  |  |  |
Janssen |  | ✔️ |  |  |  |
TRB Chemedica | ✔️ |  |  |  |  |
IBSA |  | ✔️ |  |  |  |

**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**

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Dr. Berenbaum reports personal fees from Flexion, during the conduct of the study; other from Flexion, personal fees from Pfizer, personal fees from AbbVie, personal fees from MerckSerono, grants and personal fees from Servier, personal fees from Expanscience, personal fees from Sanofi, personal fees from UCB, personal fees from Novartis, personal fees from Biogaran, personal fees from Biogen, personal fees from Janssen, grants from TRB Chemedica, personal fees from IBSA, outside the submitted work.

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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)  
   Jay

2. Surname (Last Name)  
   Lieberman

3. Date  
   20-April-2017

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

Corresponding Author’s Name
   Philip Conaghan

5. Manuscript Title
   Effects of a Single Intra-Articular Injection of a Microsphere-Formulation of Triamcinolone Acetonide on Knee Osteoarthritis Pain. A double-blind, randomized, placebo-controlled, multinational study

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

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

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Dr. Lieberman reports other from DePuy, Inc., outside the submitted work.

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ICMJE Form for Disclosure of Potential Conflicts of Interest

Section 1. Identifying Information

1. Given Name (First Name)  
   Joelle

2. Surname (Last Name)  
   Lufkin

3. Date  
   14-December-2016

4. Are you the corresponding author?  
   ☑ No

Corresponding Author’s Name  
   Philip G. Conaghan

5. Manuscript Title  
   Effects of a single intra-articular injection of a microsphere-formulation of triamcinolone acetonide on knee osteoarthritis pain. A double-blind, randomized, placebo-controlled, multinational study

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Dr. Lufkin reports other from Flexion Therapeutics, outside the submitted work.

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**Section 1. Identifying Information**

1. Given Name (First Name)  
   JAMES  
2. Surname (Last Name)  
   JOHNSON  
3. Date  
   24-April-2017  
4. Are you the corresponding author?  
   Yes ✔ No  
5. Manuscript Title  
   Effects of a Single Intra-Articular Injection of a Microsphere-Formulation of Triamcinolone Acetonide on Knee Osteoarthritis Pain: A double-blind, randomized, placebo-controlled, multinational study  
6. Manuscript Identifying Number (if you know it)

**Corresponding Author’s Name**  
Philip G Conaghan MBBS PhD FRACP FRCP

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Section 6. Disclosure Statement
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Dr. JOHNSON reports personal fees from FLEXION THERAPEUTICS, during the conduct of the study; personal fees from ACURA PHARMACEUTICALS, personal fees from IROKO PHARMACEUTICALS, personal fees from IX BIOPHARMA, 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) Neil
2. Surname (Last Name) Bodick
3. Date 20-April-2017

4. Are you the corresponding author? Yes ☑ No

Corresponding Author’s Name
Philip Conaghan

5. Manuscript Title
Effects of a Single Intra-Articular Injection of a Microsphere-Formulation of Triamcinolone Acetonide on Knee Osteoarthritis Pain. A double-blind, randomized, placebo-controlled, multinational study

6. Manuscript Identifying Number (if you know it)

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Are there any relevant conflicts of interest? Yes ☑ No

Section 4. Intellectual Property -- Patents & Copyrights

Do you have any patents, whether planned, pending or issued, broadly relevant to the work? 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.

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

Employed by and hold equity in Flexion Therapeutics

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Dr. Bodick reports In addition, Dr. Bodick has a patent Corticosteroids for the treatment of joint pain pending to Flexion Therapeutics, a patent Corticosteroid formulations for maintaining corticosteroid synovial fluid concentrations pending to Flexion Therapeutics, a patent Corticosteroid formulations and methods for the treatment of joint pain in patients with type 2 diabetes pending to Flexion Therapeutics, and a patent Corticosteroid formulations and methods for the treatment of joint pain in patients with diabetes pending to Flexion Therapeutics and Employed by and hold equity in Flexion Therapeutics.
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ICMJE Form for Disclosure of Potential Conflicts of Interest

Section 1. Identifying Information

1. Given Name (First Name) Nathaniel
2. Surname (Last Name) Katz
3. Date 20-April-2017
4. Are you the corresponding author? ✔ No

5. Manuscript Title
Effects of a Single Intra-Articular Injection of a Microsphere-Formulation of Triamcinolone Acetonide on Knee Osteoarthritis Pain. A double-blind, randomized, placebo-controlled, multinational study

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Are there any relevant conflicts of interest? ✔ No

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Section 1. Identifying Information

1. Given Name (First Name)  Philip
2. Surname (Last Name)  Conaghan
3. Date  25-January-2017
4. Are you the corresponding author?  Yes  No

5. Manuscript Title
Effects of a Single Intra-Articular Injection of a Microsphere-Formulation of Triamcinolone Acetonide on Knee Osteoarthritis Pain

6. Manuscript Identifying Number (if you know it)

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Are there any relevant conflicts of interest?  Yes  No

If yes, please fill out the appropriate information below.

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**Section 1. Identifying Information**

1. Given Name (First Name)  
   Stanley

2. Surname (Last Name)  
   Cohen

3. Date  
   20-April-2017

4. Are you the corresponding author?  
   Yes ✔

5. Manuscript Title  
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Definitions.

Entity: government agency, foundation, commercial sponsor, academic institution, etc.
Grant: A grant from an entity, generally [but not always] paid to your organization
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) Virginia
2. Surname (Last Name) Kraus
3. Date 07-December-2016
4. Are you the corresponding author? No
5. Manuscript Title Effects of a single intra-articular injection of a microsphere-formulation of triamcinolone acetonide on knee osteoarthritis pain
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

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.

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<tr>
<td>Flexion Therapeutics</td>
<td></td>
<td>✓</td>
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<td></td>
<td>Consulting fees (&lt;$5000/year) received to assist with data interpretation</td>
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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? No

Section 4. Intellectual Property -- Patents & Copyrights

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

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.

Section 6. Disclosure Statement

Based on the above disclosures, this form will automatically generate a disclosure statement, which will appear in the box below.

Dr. Kraus reports personal fees from Flexion Therapeutics, during the conduct of the study.

Evaluation and Feedback

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