

## 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.

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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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#### Definitions.

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**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) Zoheb	2. Surname (Last Name) Kazi	3. Date 28-May-2017
4. Are you the corresponding author? <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No		Corresponding Author's Name Priya S. Kishnani
5. Manuscript Title Sustained immune tolerance induction in CRIM-negative Pompe patients: Ten years of experience from an international cohort		
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

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
Genzyme Corporation (Sanofi Aventis)	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	This research was supported by a grant from the Genzyme Corporation, a Sanofi Company (Cambridge, MA), and in part by the Lysosomal Disease Network (U54NS065768) is a part of the National Institutes of Health (NIH) Rare Disease Clinical Research Network (RDCRN), supported through collaboration between the NIH Office of Rare Diseases Research (ORDR) at the National Center for Advancing Translational Science (NCATS), the National Institute of Neurological Disorders and Stroke (NINDS) and National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK). The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institute of Health. The funders had no role in study design, data collection and analysis, decision to publish, or preparation of the manuscript.

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NIH	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	This research was supported by a grant from the Genzyme Corporation, a Sanofi Company (Cambridge, MA), and in part by the Lysosomal Disease Network (U54NS065768) is a part of the National Institutes of Health (NIH) Rare Disease Clinical Research Network (RDCRN), supported through collaboration between the NIH Office of Rare Diseases Research (ORDR) at the National Center for Advancing Translational Science (NCATS), the National Institute of Neurological Disorders and Stroke (NINDS) and National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK). The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institute of Health. The funders had no role in study design, data collection and analysis, decision to publish, or preparation of the manuscript.

### Section 3. Relevant financial activities outside the submitted work.

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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



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### Section 5. Relationships not covered above

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Dr. Kazi reports grants from Genzyme Corporation (Sanofi Aventis), grants from NIH, during the conduct of the study; .

### 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) Ankit	2. Surname (Last Name) Desai	3. Date 28-May-2017
4. Are you the corresponding author?	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Corresponding Author's Name Priya S. Kishnani
5. Manuscript Title Sustained immune tolerance induction in CRIM-negative Pompe patients: Ten years of experience from an international cohort		
6. Manuscript Identifying Number (if you know it)		

### Section 2. The Work Under Consideration for Publication

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Are there any relevant conflicts of interest?  Yes  No

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Dr. Desai has nothing to disclose.

### 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)  
Kathryn

2. Surname (Last Name)  
Berrier

3. Date  
28-May-2017

4. Are you the corresponding author?  Yes  No

Corresponding Author's Name  
Priya S. Kishnani

5. Manuscript Title  
Sustained immune tolerance induction in CRIM-negative Pompe patients: Ten years of experience from an international cohort

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Dr. Berrier has nothing to disclose.

### Evaluation and Feedback

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## ICMJJE Form for Disclosure of Potential Conflicts of Interest

### Section 1. Identifying Information

1. Given Name (First Name) 2. Surname (Last Name) 3. Date  
 Robert Troxler 22-February-2017

4. Are you the corresponding author?  Yes  No Corresponding Author's Name

5. Manuscript Title  
 Safe and sustained immune tolerance induction in a large international cohort of enzyme replacement therapy treated CRIM-negative infantile Pompe disease: Long-term experience  
 6. Manuscript Identifying Number (if you know it)

CRIM-negative infantile Pompe disease: Long-term experience  
 Safe and sustained immune tolerance induction in a large international cohort of enzyme replacement therapy treated

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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

If yes, please fill out the appropriate information below.

Name of Entity	Grant?	Personal Fees?	Non-Financial Support?	Other?	Comments
Sanofi Genzyme	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	The institution received less than \$1,000 to support a Pompe data registry.

### 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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Dr. Troxler reports grants totaling less than \$1,000 from Sanofi Genzyme 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)  
Raymond

2. Surname (Last Name)  
Wang

3. Date  
28-May-2017

4. Are you the corresponding author?

Yes  No

Corresponding Author's Name  
Priya S. Kishnani

5. Manuscript Title

Sustained immune tolerance induction in CRIM-negative Pompe patients: Ten years of experience from an international cohort

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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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## ICMJE Form for Disclosure of Potential Conflicts of Interest

### Section 1. Identifying Information

1. Given Name (First Name) Omar	2. Surname (Last Name) Abdul-Rahman	3. Date 20-February-2017
4. Are you the corresponding author?	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Corresponding Author's Name Priya S. Kishnani
5. Manuscript Title Immune tolerance induction experience in CRIM-negative Pompe disease patients		
6. Manuscript Identifying Number (if you know it)		

### Section 2. The Work Under Consideration for Publication

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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

### 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 6. Disclosure Statement

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Dr. Abdul-Rahman has nothing to disclose.

### 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)  
Pranoot

2. Surname (Last Name)  
Tanpaiboon

3. Date  
18-February-2017

4. Are you the corresponding author?

Yes  No

Corresponding Author's Name  
Priya S Kishnani

5. Manuscript Title

Safe and sustained immune tolerance induction in a large international cohort of enzyme replacement therapy treated CRIM-negative infantile Pompe disease: Long-term experience

6. Manuscript Identifying Number (if you know it)

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I had received honoraria and travel support from Edimer, Genzyme-Sanofi and BioMarin pharmaceuticals. I am a Principal investigator of several pharmaceutical-sponsored clinical trials including Edimer, Genzyme-Sanofi, BioMarin, Ultragenyx and Shire clinical trials and a co-investigator of NIH-funded research. **I have not had any financial interests, including stock ownership and payment for consulting, with any pharmaceutical company.**

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## ICMJE Form for Disclosure of Potential Conflicts of Interest

### Section 1. Identifying Information

1. Given Name (First Name)  
Nancy

2. Surname (Last Name)  
Mendelsohn

3. Date  
25-May-2017

4. Are you the corresponding author?  Yes  No Corresponding Author's Name

5. Manuscript Title  
Sustained immune tolerance induction in CRIM-negative Pompe patients: Ten years of experience from an international cohort

6. Manuscript Identifying Number (if you know it)

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Dr Mendelsohn is engaged in ongoing research projects with Shire, Genzyme Corporation and BioMarin

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## ICMJE Form for Disclosure of Potential Conflicts of Interest

### Section 1. Identifying Information

1. Given Name (First Name) David	2. Surname (Last Name) Kronn	3. Date 28-May-2017
4. Are you the corresponding author?	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Corresponding Author's Name Priya S. Kishnani
5. Manuscript Title Sustained immune tolerance induction in CRIM-negative Pompe patients: Ten years of experience from an international cohort		
6. Manuscript Identifying Number (if you know it)		

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Dr. Kronn has nothing to disclose.

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### Section 1. Identifying Information

1. Given Name (First Name)  
Eli

2. Surname (Last Name)  
Herskovitz

3. Date  
27-May-2017

4. Are you the corresponding author?

Yes  No

Corresponding Author's Name  
Priya S. Kishnani

5. Manuscript Title

Sustained immune tolerance induction in CRIM-negative Pompe patients: Ten years of experience from an international cohort

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Dr. Herskovitz has nothing to disclose.

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

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## ICMJE Form for Disclosure of Potential Conflicts of Interest

### Section 1. Identifying Information

1. Given Name (First Name) Michal	2. Surname (Last Name) Inbar-Feigenberg	3. Date 04-March-2017
4. Are you the corresponding author?	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Corresponding Author's Name Priya S. Kishnani
5. Manuscript Title Safe and sustained immune tolerance induction in a large international cohort of enzyme replacement therapy treated CRIM-negative infantile Pompe disease: Long-term experience		
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

### 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.

Name of Entity	Grant?	Personal Fees?	Non-Financial Support?	Other?	Comments
Sanofi Genzyme	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	

### 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

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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. Inbar-Feigenberg reports grants and non-financial support from Sanofi Genzyme, 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)  
Catherine

2. Surname (Last Name)  
Ward-Melver

3. Date  
26-May-2017

4. Are you the corresponding author?  Yes  No

Corresponding Author's Name  
Priya S. Kishnani, MD

5. Manuscript Title  
Sustained immune tolerance induction in CRIM-negative Pompe patients: Ten years of experience from an international cohort

6. Manuscript Identifying Number (if you know it)

### Section 2. The Work Under Consideration for Publication

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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

### 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

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Dr. Ward-Melver has nothing to disclose.

### 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)  
Michelle

2. Surname (Last Name)  
Polan

3. Date  
28-May-2017

4. Are you the corresponding author?  Yes  No

Corresponding Author's Name  
Priya S. Kishnani

5. Manuscript Title  
Sustained immune tolerance induction in CRIM-negative Pompe patients: Ten years of experience from an international cohort

6. Manuscript Identifying Number (if you know it)

### Section 2. The Work Under Consideration for Publication

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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

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Dr. Polan has nothing to disclose.

### 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)  
Punita

2. Surname (Last Name)  
Gupta

3. Date  
28-May-2017

4. Are you the corresponding author?

Yes  No

Corresponding Author's Name  
Priya S. Kishnani

5. Manuscript Title

Sustained immune tolerance induction in CRIM-negative Pompe patients: Ten years of experience from an international cohort

6. Manuscript Identifying Number (if you know it)

### Section 2. The Work Under Consideration for Publication

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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

### 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

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### Section 5. Relationships not covered above

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Dr. Gupta has nothing to disclose.

### 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)  
Amy

2. Surname (Last Name)  
Rosenberg

3. Date  
28-May-2017

4. Are you the corresponding author?

Yes  No

Corresponding Author's Name  
Priya S. Kishnani

5. Manuscript Title

Sustained immune tolerance induction in CRIM-negative Pompe patients: Ten years of experience from an international cohort

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Are there any relevant conflicts of interest?  Yes  No

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Dr. Rosenberg has nothing to disclose.

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1. Given Name (First Name)  
Priya

2. Surname (Last Name)  
Kishnani

3. Date  
28-May-2017

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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

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
Genzyme Corporation (Sanofi Aventis)	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Priya S. Kishnani has received research/grant support and honoraria from Genzyme Corporation. Priya S. Kishnani is a member of the Pompe and Gaucher Disease Registry Advisory Board for Genzyme Corporation.

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Name of Institution/Company	Grant?	Personal Fees?	Non-Financial Support?	Other?	Comments
NIH	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	This research was supported by a grant from the Genzyme Corporation, a Sanofi Company (Cambridge, MA), and in part by the Lysosomal Disease Network (U54NS065768) is a part of the National Institutes of Health (NIH) Rare Disease Clinical Research Network (RDCRN), supported through collaboration between the NIH Office of Rare Diseases Research (ORDR) at the National Center for Advancing Translational Science (NCATS), the National Institute of Neurological Disorders and Stroke (NINDS) and National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK). The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institute of Health. The funders had no role in study design, data collection and analysis, decision to publish, or preparation of the manuscript.

### 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
PTC Therapeutics	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Baebies, Inc.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	Advisory Board
Alexion Pharmaceuticals, Inc.	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Amicus Therapeutics	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Shire Pharmaceuticals	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Synageva	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	FDA Avvisory Board

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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

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.

Patent?	Pending?	Issued?	Licensed?	Royalties?	Licensee?	Comments
20150037329 (US Patent #8,809,282)	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		US Patent #8,809,282, issued August 19, 2014, "Method of Reducing Titers of Antibodies Specific for a Therapeutic Agent," Inventors: Priya S. Kishnani, Surhad C. Banugaria, Dwight D, Koeberl, Sean N. Prater.

### 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. Kishnani reports grants and personal fees from Genzyme Corporation (Sanofi Aventis), grants from NIH, during the conduct of the study; personal fees from PTC Therapeutics, other from Baebies, Inc. , personal fees from Alexion Pharmaceuticals, Inc., personal fees from Amicus Therapeutics, grants and personal fees from Shire Pharmaceuticals, personal fees from Synageva, outside the submitted work; In addition, Dr. Kishnani has a patent 20150037329 (US Patent #8,809,282 issued.



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### Evaluation and Feedback

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