

#### **Instructions**

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earning royalties or not

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

patent

Dhruva 1



Section 1.	Identifying Inform	nation							
1. Given Name (Firs Sanket	it Name)	2. Surname (Last Nam Dhruva	e)	3. Date 21-March-2018					
4. Are you the corre	esponding author?	☐ Yes ✓ No	Corresponding Au Joshua D Wallacl						
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 Iden BMJ.2018.043625	tifying Number (if you kr	now it)							
		onsideration for Pu							
any aspect of the su statistical analysis, e	ibmitted work (including etc.)?	g but not limited to grant	s, data monitoring board,	ment, commercial, private foundation, e study design, manuscript preparation,	etc.) for				
Are there any rele	vant conflicts of intere	est? ☐ Yes 🗸 N	0						
Section 3.									
Section 5.	Relevant financial	activities outside tl	ne submitted work.						
of compensation)	with entities as descr	ibed in the instructions	s. Use one line for each	ncial relationships (regardless of am entity; add as many lines as you nee the 36 months prior to publicatior	ed by				
•	vant conflicts of intere		0						
If yes, please fill of	ut the appropriate info	ormation below.							
Name of Entity		Grant? Personal Fees?	Non-Financial Other	.? Comments					
Food & Drug Administ Evaluation and Resear	ration, Center for Drug ch			Reimbursement for travel only					
Section 4.	Intellectual Prope	rty Patents & Cop	yrights						
Do you have any	patents, whether plan	ned, pending or issued	l, broadly relevant to tl	ne work? ☐ Yes 🗸 No					

Dhruva 2



Section 5.	
Section 5.	Relationships not covered above
	elationships or activities that readers could perceive to have influenced, or that give the appearance of ncing, what you wrote in the submitted work?
Yes, the follow	wing relationships/conditions/circumstances are present (explain below):
✓ No other rela	tionships/conditions/circumstances that present a potential conflict of interest
	anuscript acceptance, journals will ask authors to confirm and, if necessary, update their disclosure statements. rnals may ask authors to disclose further information about reported relationships.
Section 6.	Disclosure Statement
Based on the abo	ove disclosures, this form will automatically generate a disclosure statement, which will appear in the box
Dr. Dhruva repoi submitted work;	rts other from Food & Drug Administration, Center for Drug Evaluation and Research, outside the .

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Dhruva 3



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

Egilman 1



Section 1. Identifying Inform								
Identifying Information	ation							
Given Name (First Name)     Alexander	2. Surname (Last Name Egilman	2)	3. Date 20-March-2018					
4. Are you the corresponding author?	Yes ✓ 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 Co	nsideration for Pul	blication						
Did you or your institution <b>at any time</b> received any aspect of the submitted work (including statistical analysis, etc.)?  Are there any relevant conflicts of interest of the submitted work (including statistical analysis, etc.)?  Are there any relevant conflicts of interest of the submitted work (including statistical analysis, etc.)?	but not limited to grants st?  Yes  No rmation below. If you I	s, data monitoring board, sto	udy design, manuscript preparation,					
Name of Institution/Company	Grant? Personal Fees?	Non-Financial Support?	Comments					
aura and John Arnold Foundation	<b>V</b>		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 a	activities outside th	ne submitted work.						
Place a check in the appropriate boxes ir of compensation) with entities as descrik clicking the "Add +" box. You should rep Are there any relevant conflicts of interes	n the table to indicate oped in the instructions ort relationships that w	whether you have financ . Use one line for each er were <b>present during the</b>	ntity; add as many lines as you need by					

Egilman 2



Section 4. Intellectual Property Patents & Copyrights
Do you have any patents, whether planned, pending or issued, broadly relevant to the work? Yes Vo
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):
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Mr. Egilman reports grants from Laura and John Arnold Foundation, during the conduct of the study.

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McCarthy 1



Section 1.	Identifying Inform	ation							
1. Given Name (Fi Margaret E.	rst Name)	2. Surname (Last McCarthy	Name)	3. Date 26-March-2018	}				
4. Are you the cor	responding author?	Yes ✓ N	•	ling Author's Name Nallach, 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 Idea BMJ.2018.04362	ntifying Number (if you kn 5	ow it)							
	ı								
Section 2.	The Work Under Co	onsideration fo	Publication						
Did you or your institution <b>at any time</b> 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 Institut		Grant? Person		Other? Comments					
aura and John Arno	ld Foundation	<b>/</b>		grant to the Collaborati Research Integrity and T Yale University					
Section 3.	Relevant financial	activities outsic	le the submitted <b>v</b>	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 <b>present during the 36 months prior to publication</b> .  Are there any relevant conflicts of interest? Yes Vo									
South on A									
Section 4.	Intellectual Proper	ty Patents & (	Copyrights						
Do you have any	patents, whether plani	ned, pending or is	sued, broadly releva	nt to the work? Yes	No				

McCarthy 2



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Section 1. Identifying Inform	ation							
1. Given Name (First Name) Jennifer	2. Surname (Last Name) Miller		3. Date 27-March-2018					
4. Are you the corresponding author?	Yes ✓ 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								
	onsideration for Public							
Did you or your institution <b>at any time</b> receivany aspect of the submitted work (including statistical analysis, etc.)?  Are there any relevant conflicts of intere	but not limited to grants, da							
If yes, please fill out the appropriate info Excess rows can be removed by pressing		e more than one enti	ity press the "ADD" button to add a row.					
Name of Institution/Company	Giant	n-Financial other?	Comments					
The Laura and John Arnold Foundation			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.					
Section 3. Relevant financial a	activities outside the s	submitted work.						
Place a check in the appropriate boxes in of compensation) with entities as descril clicking the "Add +" box. You should rep Are there any relevant conflicts of intere If yes, please fill out the appropriate info	bed in the instructions. Use ort relations hips that we st?	se one line for each er	ntity; add as many lines as you need by					



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Intellectual Propert	y Pate	ents & Co <sub>l</sub>	byrights					
Do you have any patents, whether plann	ed, pend	ing or issue	ed, broadly releva	nt to the	work? Yes No			
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Section 1							
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Name of Institution/Company	Giant	n-Financial other?	Comments				
he Laura and John Arnold Foundation	<b>V</b>		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. Polyment financial							
Place a check in the appropriate boxes i of compensation) with entities as descriclicking the "Add +" box. You should repart there any relevant conflicts of interesting the second conflicts of interesting the s	bed in the instructions. Us port relationships that wer est?	ether you have financ se one line for each ei	ntity; add as many lines as you need by				



Name of Entity	Grant?	Personal Fees?	Non-Financial Support?	Other?	Comments
Food and Drug Administration (FDA)	<b>✓</b>				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.	<b>V</b>				Dr. Ross receives support from Medtronic, Inc. through a research grant to determine best practices in medical device post-market surveillance.
Johnson & Johnson	<b>V</b>				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)	<b>V</b>				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)	<b>V</b>				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)	<b>V</b>				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)	<b>✓</b>				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	<b>✓</b>				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)	<b>✓</b>				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.



Section 4. Int	ellectual Property Patents & Copyrights							
Do you have any pate	ents, whether planned, pending or issued, broadly relevant to the work? Yes Vo							
Section 5. Re	lationships not covered above							
Are there other relati	onships or activities that readers could perceive to have influenced, or that give the appearance of g, what you wrote in the submitted work?							
Yes, the following	relationships/conditions/circumstances are present (explain below):							
✓ No other relation:	ships/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. Dis	sclosure Statement							
Based on the above of below.	lisclosures, this form will automatically generate a disclosure statement, which will appear in the box							
Drug Administration and Medicaid Service Administration (FDA	ts from The Laura and John Arnold Foundation, during the conduct of the study; grants from Food and (FDA), grants from Medtronic, Inc., grants from Johnson & Johnson, grants from Centers for Medicare es (CMS), grants from Blue Cross-Blue Shield Association (BCBSA), grants from Food and Drug ), grants from Agency for Healthcare Research and Quality (AHRQ), grants from Laura and John Arnold rom National Institutes of Health (NIH/NHLBI), outside the submitted work;							

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## Identifying information.

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

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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.

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

Schwartz 1



Section 1.	Identifying Inform	ation								
1. Given Name (Fir Lisa	st Name)	2. Surnam Schwartz	e (Last Nan	ne)	3. Date 19-March-2018					
4. Are you the corr	corresponding author? Yes Vo 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 Iden BMJ.2018.043625	itifying Number (if you kn	ow it)								
Section 2.	The Work Under Co	nsiderati	on for Pu	ublication						
Did you or your institution <b>at any time</b> 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  Volume  Yes										
Section 3.	Relevant financial a	activities	outside t	he 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 <b>present during the 36 months prior to publication</b> .  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				
nformulary, Inc.					<b>√</b>	Co-founder, ceased operations in December 2016				
Cassey Fellers					<b>√</b>	Medical expert in testosterone litigation				
Section 4.	Intellectual Proper	ty Pater	nts & Cop	yrights						
Do you have any patents, whether planned, pending or issued, broadly relevant to the work?										

Schwartz 2



Section 5.	
Section 5.	Relationships not covered above
	elationships or activities that readers could perceive to have influenced, or that give the appearance of ncing, what you wrote in the submitted work?
Yes, the follow	wing relationships/conditions/circumstances are present (explain below):
No other rela	tionships/conditions/circumstances that present a potential conflict of interest
	nuscript acceptance, journals will ask authors to confirm and, if necessary, update their disclosure statements rnals may ask authors to disclose further information about reported relationships.
Section 6.	Disclosure Statement
Based on the abo	ve disclosures, this form will automatically generate a disclosure statement, which will appear in the box
Informulary, I	has served as medical experts in testosterone litigation and was the cofounder of nc., a company that provided data about the benefits and harms of prescription drugs, operations in December 2016.

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earning royalties or not

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

patent



Section 1. Identifying Inform	ation					
1. Given Name (First Name) Joshua	2. Surname (Last Na Wallach	me)	3. Date 27-March-2018			
4. Are you the corresponding author?	✓ Yes No					
5. Manuscript Title Postmarket studies required by the US I and 2012: cross-sectional evaluation	Food and Drug Adm	inistration for nev	v drugs aı	nd biologics approved between 2009		
6. Manuscript Identifying Number (if you kn BMJ.2018.043625	ow it)					
Section 2. The Work Under Co	onsideration for F	Publication				
Did you or your institution <b>at any time</b> recei any aspect of the submitted work (including statistical analysis, etc.)? Are there any relevant conflicts of interei If yes, please fill out the appropriate info Excess rows can be removed by pressing	est? Yes commation below. If you	nts, data monitoring  No  pu have more than	g board, st	tudy design, manuscript preparation, ity press the "ADD" button to add a row		
Name of Institution/Company	Grant? Personal Fees?	Support?	Other?	Comments		
he Laura and John Arnold Foundation	<b>/</b>			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.			
Place a check in the appropriate boxes i of compensation) with entities as descriclicking the "Add +" box. You should repart there any relevant conflicts of interesting the propriate info	bed in the instruction ort relationships the est? Yes	ns. Use one line fo	or each er	ntity; add as many lines as you need by		



Name of Entity	Grant?	Personal Fees?	Non-Financial Support?	Other?	Comments	
The Laura and John Arnold Foundation	<b>√</b>				Dr. Wallach received research support through the Meta Research Innovation Center at Stanford (METRICS) from the Laura and John Arnold Foundation	
Section 4						
Section 4. Intellectual Propert	y Pate	ents & Cop	pyrights			
Do you have any patents, whether plann	ed, pend	ing or issue	ed, broadly releva	nt to the	work? ☐ Yes ✓ No	
Section 5. Polotionships not a						
Are there other relationships or activities			perceive to have i	nfluence	d or that give the appearance of	
potentially influencing, what you wrote i				imuence	a, or that give the appearance of	
Yes, the following relationships/cond	Yes, the following relationships/conditions/circumstances are present (explain below):					
✓ No other relationships/conditions/cir	cumstan	ces that pre	esent a potential o	conflict o	finterest	
At the time of manuscript acceptance, jo						ents.
On occasion, journals may ask authors to	aisclose	turtner info	ormation about re	eported re	eiationsnips.	
Section 6. Disclosure Stateme	nt					
Based on the above disclosures, this form		omatically	generate a disclos	sure state	ment, which will appear in the box	
below.		<del></del> ;	,		, за предамення в поставом	
Dr. Wallach reports grants from The Laur Laura and John Arnold Foundation, out:				ng the co	nduct of the study; grants from The	



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patent

Woloshin 1



Section 1. Identifying Inform					
Identifying Inform	nation				
1. Given Name (First Name) Steven	2. Surname (Last Name) Woloshin			3. Date 19-March-2018	
4. Are you the corresponding author?	Yes	Yes No Corresponding Author's No Joshua D Wallach, PhD			
5. Manuscript Title Postmarket studies required by the US I and 2012: cross-sectional evaluation	Food and D	rug Admir	nistration for new	drugs an	d biologics approved between 2009
6. Manuscript Identifying Number (if you kr BMJ.2018.043625	now it)				
Section 2. The Work Under Co	onsiderat	ion for Pu	ublication		
statistical analysis, etc.)? Are there any relevant conflicts of interest.  Section 3.  Relevant financial.		'es ✓ ſ			
Relevant financial	activities	outside t	he submitted	work.	
Place a check in the appropriate boxes i of compensation) with entities as descri clicking the "Add +" box. You should rep Are there any relevant conflicts of intered If yes, please fill out the appropriate info	ibed in the port relationest?	instruction nships that 'es	s. Use one line fo	or each en	tity; add as many lines as you need b
Name of Entity	Grant?	Personal Fees?	Non-Financial Support?	Other?	Comments
loss, Feller, Casey (law firm)		<b>✓</b>			Medical experts in testosterone litigation (against testosterone manufacturers)
nformulary, Inc.				<b>✓</b>	Co-founder of Informulary, a company which summarized drug evidence. The company ceased operations in December 2016

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