Date:5/7/2021			
Your Name:Sarah F. Maloney			
Manuscript Title: Randomized controlled trials using electronic nicotine delivery			
systems as smoking cessation aids require an accurate, empirically-based			
understanding of the nicotine delivery profile of the products under study.			
Manuscript number (if known): JPHE-20-124			

In the interest of transparency, we ask you to disclose all relationships/activities/interests listed below that are related to the content of your manuscript. "Related" means any relation with for-profit or not-for-profit third parties whose interests may be affected by the content of the manuscript. Disclosure represents a commitment to transparency and does not necessarily indicate a bias. If you are in doubt about whether to list a relationship/activity/interest, it is preferable that you do so.

The following questions apply to the author's relationships/activities/interests as they relate to the <u>current</u> <u>manuscript only</u>.

The author's relationships/activities/interests should be <u>defined broadly</u>. For example, if your manuscript pertains to the epidemiology of hypertension, you should declare all relationships with manufacturers of antihypertensive medication, even if that medication is not mentioned in the manuscript.

		Name all entities with whom you have this relationship or indicate none (add rows as needed)	Specifications/Comments (e.g., if payments were made to you or to your institution)
		Time frame: Since the initial	
1	All support for the present manuscript (e.g., funding, provision of study materials, medical writing, article	US FDA/NIH-NIDA U54DA036105 F31DA047018	Institution
	processing charges, etc.)		
	No time limit for this item.		
		Time frame: past	36 months
2	Grants or contracts from any entity (if not indicated in item #1 above).	_XNone	
3	Royalties or licenses	XNone	
4	Consulting fees	XNone	

5	Payment or honoraria for lectures, presentations,	X_None
	speakers bureaus, manuscript writing or educational events	
6	Payment for expert testimony	_XNone
7	Support for attending meetings and/or travel	X_None
8	Patents planned, issued or	X None
0	pending	
9	Participation on a Data Safety Monitoring Board or Advisory Board	XNone
10	Leadership or fiduciary role in other board, society, committee or advocacy	XNone
11	group, paid or unpaid Stock or stock options	X None
12	Receipt of equipment, materials, drugs, medical writing, gifts or other services	X_None
13	Other financial or non- financial interests	XNone

The author receives funding from the FDA and NIH through a center grant (U54DA036105) and a training fellowship (F31DA047018).

Please place an "X" next to the following statement to indicate your agreement:

_X__ I certify that I have answered every question and have not altered the wording of any of the questions on this form.

Date: 05/07/21

Your Name: Cosima Hoetger

Manuscript Title: Randomized controlled trials using electronic nicotine delivery systems as smoking cessation aids require an accurate, empirically-based understanding of the nicotine delivery profile of the products under study **Manuscript number (if known):** JPHE-20-124

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		Name all entities with whom you have this relationship or indicate none (add rows as needed)	Specifications/Comments (e.g., if payments were made to you or to your institution)
		Time frame: Since the initial	planning of the work
1	All support for the present	NIH/FDA U54DA036105	
	manuscript (e.g., funding,		
	provision of study materials,		
	medical writing, article		
	processing charges, etc.)		
	No time limit for this item.		
		Time frame: past	36 months
2	Grants or contracts from	<u>X</u> None	
	any entity (if not indicated		
	in item #1 above).		
3	Royalties or licenses	<u>X</u> None	
4	Consulting fees	<u>X</u> None	

5	Payment or honoraria for lectures, presentations, speakers bureaus,	X_None	
	manuscript writing or educational events		
6	Payment for expert testimony	X None	
7	Support for attending meetings and/or travel	<u>X</u> None	
8	Patents planned, issued or pending	X None	
9	Participation on a Data Safety Monitoring Board or	X_None	
10	Advisory Board Leadership or fiduciary role	V Nono	
10	in other board, society,	<u>X</u> None	
	committee or advocacy group, paid or unpaid		
11	Stock or stock options	<u>X</u> None	
12	Receipt of equipment,	X None	
	materials, drugs, medical		
	writing, gifts or other services		
13	Other financial or non-	<u>X</u> None	
	financial interests		

The author receives funding from the FDA and NIH through a center grant (U54DA036105).

Please place an "X" next to the following statement to indicate your agreement:

<u>X</u> I certify that I have answered every question and have not altered the wording of any of the questions on this form.

Date:5/7/2021		
Your Name:Alyssa Rudy		
Manuscript Title: Randomized controlled trials using electronic nicotine delivery		
systems as smoking cessation aids require an accurate, empirically-based		
understanding of the nicotine delivery profile of the products under study.		
Manuscript number (if known): JPHE-20-124		

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		Name all entities with whom you have this relationship or indicate none (add rows as needed)	Specifications/Comments (e.g., if payments were made to you or to your institution)
		Time frame: Since the initial	planning of the work
1	All support for the present	NIH/FDA	Institution
	manuscript (e.g., funding,	U54DA036105	
	provision of study materials,		
	medical writing, article		
	processing charges, etc.)		
	No time limit for this item.		
		Time frame: past	36 months
2	Grants or contracts from	_XNone	
	any entity (if not indicated		
	in item #1 above).		
3	Royalties or licenses	XNone	

4	Consulting fees	XNone
5	Payment or honoraria for lectures, presentations, speakers bureaus, manuscript writing or educational events	XNone
6	Payment for expert testimony	_XNone
7	Support for attending meetings and/or travel	X_None
8	Patents planned, issued or pending	X_None
9	Participation on a Data Safety Monitoring Board or Advisory Board	XNone
10	Leadership or fiduciary role in other board, society, committee or advocacy group, paid or unpaid	XNone
11	Stock or stock options	XNone
12	Receipt of equipment, materials, drugs, medical writing, gifts or other services	X_None
13	Other financial or non- financial interests	XNone

The author receives funding from the FDA and NIH from a center grant (U54DA036105).

Please place an "X" next to the following statement to indicate your agreement:

_X__ I certify that I have answered every question and have not altered the wording of any of the questions on this form.

Date: 05/7/2021

Your Name: Alisha Eversole

Manuscript Title:<u>Randomized controlled trials using electronic nicotine delivery systems as smoking cessation aids</u> require an accurate, empirically-based understanding of the nicotine delivery profile of the products under study. Manuscript number (if known):_JPHE-20-124

In the interest of transparency, we ask you to disclose all relationships/activities/interests listed below that are related to the content of your manuscript. "Related" means any relation with for-profit or not-for-profit third parties whose interests may be affected by the content of the manuscript. Disclosure represents a commitment to transparency and does not necessarily indicate a bias. If you are in doubt about whether to list a relationship/activity/interest, it is preferable that you do so.

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		Name all entities with whom you have this relationship or indicate none (add rows as needed)	Specifications/Comments (e.g., if payments were made to you or to your institution)
		Time frame: Since the initial	planning of the work
1	All support for the present	NIH/FDA U54DA036105	
	manuscript (e.g., funding,		
	provision of study materials,		
	medical writing, article		
	processing charges, etc.)		
	No time limit for this item.		
		Time frame: past	36 months
2	Grants or contracts from	XNone	
	any entity (if not indicated		
	in item #1 above).		
3	Royalties or licenses	XNone	
4	Consulting fees	XNone	

5		V. Nere	
5	Payment or honoraria for lectures, presentations,	XNone	
	speakers bureaus,		
	manuscript writing or		
	educational events		
6	Payment for expert	_XNone	
	testimony		
7	Support for attending meetings and/or travel	XNone	
	meetings and/or traver		
8	Patents planned, issued or	_XNone	
	pending		
9	Participation on a Data	X None	
5	Safety Monitoring Board or		
	Advisory Board		
10	Leadership or fiduciary role	_XNone	
	in other board, society,		
	committee or advocacy		
	group, paid or unpaid		
11	Stock or stock options	XNone	
12	Descipt of equipment	V. News	
12	Receipt of equipment,	XNone	
	materials, drugs, medical writing, gifts or other		
	services		
13	Other financial or non-	X None	
	financial interests		
	•		

The author receives funding from the FDA and NIH from a center grant (U54DA036105).

Please place an "X" next to the following statement to indicate your agreement:

<u>X</u> I certify that I have answered every question and have not altered the wording of any of the questions on this form.

Date: 5/7/2021

Your Name: Ashlee Sawyer

Manuscript Title: <u>Randomized controlled trials using electronic nicotine delivery systems as smoking cessation aids</u> <u>require an accurate, empirically-based understanding of the nicotine delivery profile of the products under study.</u> Manuscript number (if known): <u>JPHE-20-124</u>

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		Name all entities with whom you have this relationship or indicate none (add rows as needed) Time frame: Since the initial	Specifications/Comments (e.g., if payments were made to you or to your institution) planning of the work
1	All support for the present manuscript (e.g., funding, provision of study materials, medical writing, article processing charges, etc.) No time limit for this item.	NIH/FDA U54DA036105	
2	Grants or contracts from any entity (if not indicated in item #1 above).	Time frame: past XNone	36 months
3	Royalties or licenses	XNone	
4	Consulting fees	XNone	

5	Payment or honoraria for lectures, presentations, speakers bureaus, manuscript writing or educational events Payment for expert testimony	_XNone
7	Support for attending meetings and/or travel	_XNone
8	Patents planned, issued or pending	XNone
9	Participation on a Data Safety Monitoring Board or Advisory Board	XNone
10	Leadership or fiduciary role in other board, society, committee or advocacy group, paid or unpaid	X_None
11	Stock or stock options	X_None
12	Receipt of equipment, materials, drugs, medical writing, gifts or other services	X_None
13	Other financial or non- financial interests	X_None

The author receives funding from the FDA and NIH through a center grant (U54DA036105).

Please place an "X" next to the following statement to indicate your agreement:

X I certify that I have answered every question and have not altered the wording of any of the questions on this form.

Date: 5/7/2021

Your Name: Caroline O. Cobb

Manuscript Title: <u>Randomized controlled trials using electronic nicotine delivery systems as smoking cessation aids</u> require an accurate, empirically-based understanding of the nicotine delivery profile of the products under study. Manuscript number (if known): <u>JPHE-20-124</u>

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		Name all entities with whom you have this relationship or indicate none (add rows as needed)	Specifications/Comments (e.g., if payments were made to you or to your institution)
		Time frame: Since the initial	planning of the work
1	All support for the present	NIH/FDA	Institution
	manuscript (e.g., funding,		
	provision of study materials,		
	medical writing, article		
	processing charges, etc.)		
	No time limit for this item.		
		Time frame: past	36 months
2	Grants or contracts from	Virginia Foundation for	Institution
	any entity (if not indicated	Healthy Youth	
	in item #1 above).	Virginia Commonwealth	Within-Institution
		University Massey Cancer	
		Center	
3	Royalties or licenses	X_None	
4	Consulting fees	_XNone	

5	Payment or honoraria for lectures, presentations, speakers bureaus, manuscript writing or	University of Arkansas for Medical Sciences Virginia Foundation for Healthy Youth	Support for attending meeting/speaking Support for attending meeting/speaking
	educational events		
6	Payment for expert testimony	_XNone	
7	Support for attending meetings and/or travel	NIH-Center for Scientific Review	Support for being grant reviewer/attending meeting
		California Tobacco- Related Disease Research Program	Support for being grant reviewer/attending meeting
0	Detents planned issued on	V. Nana	
8	Patents planned, issued or pending	XNone	
9	Participation on a Data	X None	
	Safety Monitoring Board or Advisory Board		
10	Leadership or fiduciary role	XNone	
	in other board, society,		
	committee or advocacy group, paid or unpaid		
11	Stock or stock options	Allegion Public LTD CO F; Conocophillips; General Electric CO; Honeywell International; Ingersoll Rand CL; Parker-Hannifin Corp; Phillips 66	Myself/my husband own <\$5,000 investment value in each of the following stocks.
		Porvair Filtration Group	Myself/my husband own between \$50,000-250,000 investment value in this stock (husband was previous employee).
12	Receipt of equipment,	XNone	
12	materials, drugs, medical writing, gifts or other		
10	services Other financial or non-	V Nono	
13	financial interests	_XNone	

This author and the research is supported by grant number U54DA036105 from the National Institute on Drug Abuse of the National Institutes of Health and the Center for Tobacco Products of the U.S. Food and Drug Administration.

Not related to the current work, this author has received funding from Virginia Foundation for Healthy Youth and Virginia Commonwealth University Massey Cancer Center. The author has also received University of Arkansas for Medical Sciences and Virginia Foundation for Healthy Youth for guest speaking and from NIH-Center for Scientific Review and California Tobacco-Related Disease Research Program for grant review.

Please place an "X" next to the following statement to indicate your agreement:

X I certify that I have answered every question and have not altered the wording of any of the questions on this form.

Date:	_May 7 th , 2021			
Your Name:	Andrew J. Barnes, PhD			
Manuscript Tit	Manuscript Title: Randomized controlled trials using electronic nicotine delivery systems as smoking cessation aids			
require an accurate, empirically-based understanding of the nicotine delivery profile of the products under study.				
Manuscript nu	Imber (if known): JPHE-20-124			

In the interest of transparency, we ask you to disclose all relationships/activities/interests listed below that are related to the content of your manuscript. "Related" means any relation with for-profit or not-for-profit third parties whose interests may be affected by the content of the manuscript. Disclosure represents a commitment to transparency and does not necessarily indicate a bias. If you are in doubt about whether to list a relationship/activity/interest, it is preferable that you do so.

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		Name all entities with whom you have this relationship or indicate none (add rows as needed)	Specifications/Comments (e.g., if payments were made to you or to your institution)
		Time frame: Since the initial	planning of the work
1	All support for the present manuscript (e.g., funding, provision of study materials, medical writing, article processing charges, etc.) No time limit for this item.	National Institutes of Health and US Food and Drug Administration	Institution
		Time frame: past	36 months
2	Grants or contracts from any entity (if not indicated in item #1 above).	Virginia Foundation for Healthy Youth, Centers for Medicare and Medicaid Services, Virginia Department of Medical Assistance Services	Institution

2	Develties or licenses	Toythook royaltica	
3	Royalties or licenses	Textbook royalties	
4	Consulting fees	World Health Organization, National Institutes of Health	
5	Payment or honoraria for	XNone	
	lectures, presentations,		
	speakers bureaus, manuscript writing or educational events		
6	Payment for expert	XNone	
	testimony		
_			
7	Support for attending meetings and/or travel	XNone	
	meetings and/or traver		
8	Patents planned, issued or	XNone	
	pending		
0	Participation on a Data	X None	
9	Participation on a Data Safety Monitoring Board or	XNone	
	Advisory Board		
10	Leadership or fiduciary role	XNone	
	in other board, society,		
	committee or advocacy group, paid or unpaid		
11	Stock or stock options	X None	
12	Receipt of equipment,	XNone	
	materials, drugs, medical		
	writing, gifts or other services		
13	Other financial or non-	XNone	
	financial interests		

This project was funded by NIH/FDA. The author has received funding for unrelated work from other state and federal agencies and foundations in the last 36 months. Additionally, the author has received royalties for textbooks and consulting fees from the NIH and WHO, none of these are related to the funded project or research experiences this manuscript was based upon.

Please place an "X" next to the following statement to indicate your agreement:

__X_ I certify that I have answered every question and have not altered the wording of any of the questions on this form.

Date:5.7.2021	
Your Name:Alison Breland	
Manuscript Title: Randomized controlled trials using electronic nicotine delivery systems as smoking cessation aids require an accurate, empirically-based understanding of the nicotine delivery profile of the products under study	
Manuscript number (if known): JPHE-20-124	

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		Name all entities with whom you have this relationship or indicate none (add rows as needed)	Specifications/Comments (e.g., if payments were made to you or to your institution)
		Time frame: Since the initial	planning of the work
1	All support for the present	_XNone	
	manuscript (e.g., funding,	NIH/FDA	
	provision of study materials,	U54DA036105	
	medical writing, article		
	processing charges, etc.)		
	No time limit for this item.		
		Time frame: past	36 months
2	Grants or contracts from	XNone	
	any entity (if not indicated		
	in item #1 above).		
3	Royalties or licenses	X None	

4	Consulting fees	_XNone	
-	Deverent on her evenin for	V None	
5	Payment or honoraria for lectures, presentations,	_XNone	
	speakers bureaus,		
	manuscript writing or		
	educational events		
6	Payment for expert	_XNone	
	testimony		
_			
7	Support for attending meetings and/or travel	XNone	
8	Patents planned, issued or	XNone	
	pending		
9	Participation on a Data	XNone	
	Safety Monitoring Board or Advisory Board		
10	Leadership or fiduciary role	X None	
10	in other board, society,		
	committee or advocacy		
	group, paid or unpaid		
11	Stock or stock options	_XNone	
12	Receipt of aquipment	V Nono	
12	Receipt of equipment, materials, drugs, medical	_XNone	
	writing, gifts or other		
	services		
13	Other financial or non-	XNone	
	financial interests		

The author receives funding from the FDA and NIH through a center grant (U54DA036105).

Please place an "X" next to the following statement to indicate your agreement:

_x__ I certify that I have answered every question and have not altered the wording of any of the questions on this form.

Date:	March 20, 2021
Your Nan	ne: Thomas Eissenberg
Manuscri	pt Title: Randomized controlled trials using electronic nicotine delivery systems as smoking cessation aids require
an accura	te, empirically-based understanding of the nicotine delivery profile of the products under study
Manuscri	pt number (if known):JPHE-20-124

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The author's relationships/activities/interests should be <u>defined broadly</u>. For example, if your manuscript pertains to the epidemiology of hypertension, you should declare all relationships with manufacturers of antihypertensive medication, even if that medication is not mentioned in the manuscript.

		Name all entities with whom you have this relationship or indicate none (add rows as needed)	Specifications/Comments (e.g., if payments were made to you or to your institution)
		Time frame: Since the initial	planning of the work
1	All support for the present		
	manuscript (e.g., funding,	US FDA/NIH-NIDA	Grant to VCU
	provision of study materials,		
	medical writing, article		
	processing charges, etc.) No time limit for this item.		
	No time limit for this item.		
		Time frame: past	36 months
2	Grants or contracts from		
	any entity (if not indicated	US FDA/NIH-NCI	Grant to VCU
	in item #1 above).		
3	Royalties or licenses	XNone	
4	Consulting fees		
		Migliaccio & Rathod LLP	Law firm: Plaintiff in suit against ECIG industry

5	Payment or honoraria for lectures, presentations, speakers bureaus, manuscript writing or educational events Payment for expert testimony	XNone	
7	Support for attending meetings and/or travel	_XNone	
8	Patents planned, issued or pending	Two, not licensed, not monetized in any way	one patent for a device that measures the puffing behavior of electronic cigarette users and another patent for a smartphone app that determines electronic cigarette device and liquid characteristics.
9	Participation on a Data Safety Monitoring Board or Advisory Board	XNone	
10	Leadership or fiduciary role in other board, society, committee or advocacy group, paid or unpaid	XNone	
11	Stock or stock options	Bank of America, SPYD index fund, GE, Newell brands	Privately owned stock, all unrelated to this work.
12	Receipt of equipment, materials, drugs, medical writing, gifts or other services	XNone	
13	Other financial or non- financial interests	ΤΙΑΑ	Retirement fund

This research is supported by grant number U54DA036105 from the National Institute on Drug Abuse of the National Institutes of Health and the Center for Tobacco Products of the U.S. Food and Drug Administration. The content is solely the responsibility of the authors and does not necessarily represent the views of the NIH or the FDA

Dr. Eissenberg is a paid consultant in litigation against the tobacco industry and also the electronic cigarette industry and is named on one patent for a device that measures the puffing behavior of electronic cigarette users and on another patent for a smartphone app that determines electronic cigarette device and liquid characteristics.

Please place an "X" next to the following statement to indicate your agreement:

_X__ I certify that I have answered every question and have not altered the wording of any of the questions on this form.