



REPORT INFORMATION

Report Profile

Report Version	FPSR.FDA.CTP.V.V1
Report Category	Tobacco Product Report
Submitted	2014-02-09
FDA ICSR ID	(b) (6)
Report Key for Followup	(b) (6)

Report Identifying Information

Create a name to help you find this report in the future (max length: 50 characters)	(b) (6)
Regulatory Status	Voluntary
Type of Submission	Initial
What type of report are you submitting?	Health-Related Problem associated with a tobacco product (not associated with a product problem or defect)

Contact Information - Sender

Confirm Email	(b) (6)
First Name	(b)
Last Name	(b)
Phone	(b) (6)
Email	(b) (6)
Country	United States
Street Address Line 1	(b) (6)
Street Address Line 2	<blank>
City/Town	(b)
State	Oklahoma
ZIP/Postal Code	(b) (6)
Check here if you wish to remain anonymous.	No
May the FDA contact you to follow-up if necessary?	Yes
Preferred method of contact	Email
Sender Category	Consumer/Concerned Citizen
Are you the person who experienced health problems associated with a tobacco product?	Yes
Please describe your relationship to the person who experienced the health problem	<blank>

Product Information

Brand Name or Product Name	Vapor King
Universal Product Code (UPC) from label	unknown

Did the product come from another country?	Unknown
Product Type	Other
When did the person purchase this product?	12/10/2013
Does the person still have the product?	Yes
Description of other tobacco product type	e-cigarett
Do you know where the product was purchased?	Yes
Do you know who manufactured this product?	No

Product Purchase Location

Purchase Location Name	Vapor King
Country	United States
Street Address Line 1	4305-E S. Mingo
Street Address Line 2	<blank>
City/Town	Tulsa
State	Oklahoma
ZIP/Postal Code	unknown
Phone	(918) 949-9292
How was this product purchased?	in a store
Web Address	<blank>

Manufacturer Information

Product Use Details

When did the person open the package and start using the product that may have caused the health problem? 11/08/2013

When did the person stop using the product that may have caused the health problem? 02/08/2014

How long has the person been using this brand? 3

Select Unit of Measure Months

Was the product being used when the health problem occurred? Yes

Did the person use this product before without a problem? Yes

Did the person change the product in any way before using it (for example: removing a filter from a cigarette)? No

Is the affected person currently using other tobacco products (within past month)? Yes

Does the person who had the adverse event also drink alcohol? No

Has the affected person used other tobacco products in the past? Yes

Please describe anything else you think the FDA should know about this health problem <blank>

On average, number of pieces, pinches, dips, or rubs used 1

Please select per week

Reaction and Product Relatedness

How soon after the product was last used did the health problem occur? 5

Select Unit of Measure minute(s)

Did the person stop using the product when he/she had the health problem? No

Problem Summary

Health problem start date 02/04/2014

Health problem end date 02/04/2014

How long did the health problem last (if resolved) (or if ongoing, how long has it lasted so far)? 1

Select Unit of Time hour(s)

Please describe the health problem or product problem: Seizure (verified through MRI) resulting in a 2-day hospitalization.

Do any of these apply to the health problem? (Select one or more) Hospitalization

Outcome to date Ongoing

Was the person taken to an emergency facility? Yes

Was the person evaluated by a healthcare professional? Yes

Date the person was first seen by a healthcare professional for this health problem 02/04/2014

Please describe any treatment the person received including results of any tests (such as x-rays, lab results, or blood work) Treated with IV fluids, blood thinners and anti-epileptic medication. MRI indicated a seizure had occurred.

Has the person had a similar health problem or product problem? No

Please describe the similar health problem or product problem <blank>

What are the main symptoms or health problems? (select up to 5) Other problem not listed

Affected Person

Gender Female

Pregnant No

Race (Select one or more) White

Ethnicity Not Hispanic or Latino

Birth date of the person who experienced the health problem (b) (6)

Age of the person when the health problem occurred 66

Select Unit of Age year(s)

Please list any known pre-existing health problems for the affected person Asthma, COPD, RA

Product Components

Other Products Used

Other Tobacco Products Currently Used

Brand Name or Product Name	Marlboro 72
Product Type	Cigarettes
On average, number smoked	10
Please select	per day
Duration of Use	Less than 1 month

Other Tobacco Products Used in the Past

Brand Name or Product Name	Echo
Product Type	Cigarettes
On average, number smoked	20
Please select	per day
Duration of Use	More than 12 months

Medications, Vitamins and Supplements

Please give us information about prescription medications, OTC medications, vitamins and/or supplements taken around the time of the health problem

Advair Diskus, ProAir HFA, Lexapro, Albuteral Sulfate, Aleve, Aspirin, Caltrate Calcium w/D, Clacium-magnesium-zinc, Multi Vitamin, Potasium Gluconate, Super B Complex w Vitamin C and Folic Acid, Naproxenen and Kappra,

Attached Files

None



REPORT INFORMATION

Report Profile

Report Version	FPSR.FDA.CTP.V.V2
Report Category	Tobacco Product Report V2
Submitted	2018-06-27
FDA ICSR ID	(b) (6)
Followup by using your account	(b) (6)

Proxy Report Information (not applicable if this is not a proxy report)

Report Identifying Information

Create a name to help you find this report in the future (max length: 50 characters)	(b) (6)
Regulatory Status	Voluntary
Type of Submission	Initial
What type of report are you submitting?	Health-Related Problem associated with a tobacco product (not associated with a product problem or defect)

**Did you report this problem
somewhere else (outside
SRP)?** No

Contact Information - Sender

Organization Name	<blank>
Confirm Email	(b) (6)
First Name	(b) (6)
Last Name	(b)
May the FDA share your name and contact information with the manufacturer/distributor of the tobacco product(s) described in your report?	No
May the FDA share your name and contact information with other federal government agencies (e.g. CDC, CPSC, FTC, TTB)?	No
May the FDA share your name and contact information with local or state government agencies (e.g. enforcement or public health/safety agencies)?	No
Did you report the problem to the manufacturer?	No
Job Title	<blank>
Phone	(b) (6)
Email (If prefilled, changing this email address will not change your Login email ID)	(b) (6)
Country	United States
Street Address Line 1	(b) (6)
Street Address Line 2	<blank>
City/Town	(b) (6)
State	Maryland
ZIP/Postal Code	(b) (6)
Sender Category	Consumer/Concerned Citizen (FdaTPR)

Consumer/Concerned Citizen Type (select all that apply) Concerned citizen

Are you the person who experienced health problems associated with a tobacco product? No

Describe your relationship to the person who experienced the health problem mother

Problem Summary

Problem Start Date 06/23/2018

Problem End Date 06/23/2018

Please describe the health problem or product problem. The Attachments page will accept uploads of any records, pictures, or other information.

After inhaling on a Juul device, of which I was unaware he was using, my teenage son preceded to have a grand mal seizure. He describes inhaling from the device and seeing an eye aura immediately in his left eye. The eye aura turned into a what he describes as a dark shadow coming at him that he was trying to get away from and then he remembers nothing after that. From that point I became involved as I heard him crash to the floor in the room above me. I reached him as he was fully seizing, convulsions, turning blue, eyes rolled up in his head. He was unconscious once the convulsions stopped about a minute after they probably started. He does not remember anything until starting to come to in the ambulance. Paramedics found the Juul device underneath him and when I asked him about it at the hospital, he admitted using it right before the seizure. This is a perfectly healthy teenager with no underlying issues.

Do any of these apply to the health problem? (Select one or more) Emergency room visit without hospital admission

Treatment Received (select all that apply) Healthcare Professional Visit

Please describe treatment the person received, including results of any tests (such as x-rays, lab results, or blood work). The Attachments page will accept uploads of any records, pictures, or other information. CT scan- clear; Blood work- clear; Urinalysis- clear; Drug Test- Clear All done at the hospital. Visit to his pediatrician who has ordered an EEG for a baseline reading.

How long did the health problem last (if resolved), or (if ongoing) how long has it lasted so far?

5

Select Unit of Time

day(s)

What is the current status of the health problem?

Not Recovered or Unresolved

Does the health problem include a secondhand or thirdhand effect (i.e. a health problem affecting someone other than the person using the tobacco product)?

No

Affected Person

Gender

Male

Race (Select all that apply)

White

Ethnicity

Not Hispanic or Latino

Birth date of the person who experienced the health problem

(b) (6)

Age of the person when the problem occurred

16

Select Unit of Age

year(s)

Please list any known pre-existing health problems for the affected person

none

Medications and Supplements

Please list the prescription medications, over-the-counter medications, vitamins, and/or supplements taken around the time of the health problem.

none

What are the main symptoms or health problems?

Term describing the health problem Seizure grand mal

Tobacco Products

Tobacco Product Type Electronic cigarette, electronic nicotine or vaping product(E-cigarette, e-cigars, e-hookahs, e-pipes, vape pens, hookah pens, and personal vaporizers; E-liquids, e-juice or vape juice)

Tobacco Product Subtype E-liquid, e-juice or vape juice (purchased separately)

Select all that apply to the e-liquid, e-juice or vape juice for your electronic cigarette, electronic nicotine or vaping product Purchased in a non-refillable disposable cartridge

Does the e-liquid, e-juice or vape juice contain any of the following? (select all that apply) Nicotine, Flavor(s), Glycerin, Propylene Glycol, Other

Describe other e-liquid ingredients Benzoic acid

What type(s) of flavor(s) does the e-liquid contain? (select all that apply) Mint (such as wintergreen or spearmint)

Was the e-liquid dripped on to the atomizer or heating element? Unknown

Full Tobacco Product Name, including Brand and Sub-Brand (if unknown, please enter "unknown") Juul Cool Mint 5% strength

When did the person purchase this product? <blank>

UNIVERSAL PRODUCT CODE (UPC) from Label 819913011405

Any other identifying tobacco product codes (for scannable QR code G0320WG

example, SKU, item/catalog number, manufacturing date/ batch code)

What is the country of manufacture of the tobacco product? United States

Where is the tobacco product now? User/Consumer has the product

How was this product acquired? From a Friend

Do you know where the product was purchased? No

Manufacturer Name <blank>

Tobacco Product Packaging and Portions

Manufacturer Investigation Information

Tobacco Product Purchase Location

Tobacco Product Manufacturer Information

Tobacco Product Use Details

How was the tobacco product used? Inhaled (smoked or vaped)

On average, how often is this tobacco product used?	Every Day
Are other substances being mixed in with the tobacco product when used?	<blank>
Did the problem occur with first time use of the tobacco product?	No
How long has the person been using this type of tobacco product?	1
Select Unit of Measure	Month(s)
How soon after the tobacco product was last used did the health problem occur?	5
Select Unit of Measure	Second(s)
How long has the person been using this particular brand or label?	1
Select Unit of Measure	Month(s)
Do you think this problem was caused by a particular package or unit of this product?	Yes
Did the person continue to use this tobacco product after the problem occurred?	No
Did this same or similar health problem happen again after repeat use of the tobacco product?	N/A - Person did not restart use
Did the person change the product in any way before using it (for example, removing a filter from a cigarette)?	No

Tobacco Product Parts

Full Tobacco Product Part Name, including Brand and	<blank>
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**Sub-Brand (if unknown,
please enter "unknown")**

Tobacco Product Part Type <blank>

**In your opinion, how
likely is it that the tobacco
product part is related to the
problem?** Related

**When was this tobacco
product part purchased or
acquired?** <blank>

**UNIVERSAL PRODUCT
CODE (UPC) from Label** <blank>

**Any other identifying
tobacco product part
codes(e.g. SKU, item/catalog
number)** <blank>

**What is the country of
manufacture of the tobacco
product part?** United States

**Where is the tobacco
product part now?** User/Consumer has the product

**Do you know who
manufactured this tobacco
product part?** <blank>

Tobacco Product Part Purchase Location

**How was this tobacco
product part acquired?** From a Friend

Purchase Location Name <blank>

Country United States

Phone <blank>

Street Address Line 1 <blank>

Street Address Line 2 <blank>

City/Town <blank>

State Maryland

ZIP/Postal Code <blank>

Web Address <blank>

Email Address <blank>

Tobacco Product Part Manufacturer Information

State <blank>

State/Province <blank>

Other Products Used

Has the affected person used other tobacco products (either currently or in the past)? No

Other Tobacco Products

Additional Information

Please describe anything else you think the FDA should know about this problem. Attachments may be added on the next page.

My son has said that "Everyone" in high school has a JUUL device and is vaping. He is not someone that you would expect to use it, so if he is doing it, then I believe him when he says everyone. Teenagers think this device is not harmful to them. Thinks it's "cool". Clearly something has to be done and quickly! I truly believe this product caused my son's seizure. We will be able to rule out any underlying issues with regard to his health by the end of the next three weeks, however, even if he is found to have an underlying issue, this product at the very least triggered it. However, myself and his pediatrician feel this seizure is directly related to the JUUL device and pod used. Time to fast track regulation of these devices!

Attached Files

None

All dates displayed in the report are in EST(GMT-05:00) time zone

Basic Details			
Company Unit	CDER-CTU	Originating Account	FAERS
Source Medium	MWO (Drug)	Source Form Type	E2B XML 3500B
Priority	Routine		
FDA Received Date	07-Jul-2018	CTU Received Date	07-Jul-2018
CTU Triage Date		CTU Data Entry Date	
Report Type	Spontaneous	Report Classification	Drug
Assign To	User		
User/Group			
Forward to Department	<input checked="" type="checkbox"/> CDER (CDER-OSE-RSS-CTU@fda.hhs.gov) (E2B)		
Case Priority	Direct		

Contact				
Case Reporter	First Name	Last Name	Email Address	Phone
<input checked="" type="checkbox"/>	(b) (6)	(b) (6)		

Section A - About the Problem	
What kind of problem was it? (Check all that apply)	<input checked="" type="checkbox"/> Were hurt or had a bad side effect (including new or worsening symptoms) <input type="checkbox"/> Used a product incorrectly which could have or led to a problem <input type="checkbox"/> Noticed a problem with the quality of the product <input type="checkbox"/> Had problems after switching from one product maker to another maker
Date the problem occurred	29-Jun-2018
Serious	Yes
Did any of the following happen? (Check all that apply)	<input checked="" type="checkbox"/> Hospitalization - admitted or stayed longer <input type="checkbox"/> Required help to prevent permanent harm (for medical devices only) <input type="checkbox"/> Disability or health problem <input type="checkbox"/> Birth defect <input type="checkbox"/> Life-threatening <input type="checkbox"/> Death <input type="checkbox"/> Other serious/important medical incident

Tell us what happened and how it happened (Include as many details as possible)
I used a Juul e cigarette and experienced a serious 5+ min seizure within 30min. I have never experienced a seizure before until Juul.

List any relevant tests or laboratory data if you know them (Include dates)
Admitted into ER, blood work, ct scan

Section B - About the Products		1 of 1
Suspect	Yes	
Primary?	Yes	

Product Type	Drug/Biologic		
Name of the product as it appears on the box, bottle, or package (Include as many names as you see)	Juul		
Name of the company that makes (or compounds) the product	Juul		
Is the Product Compounded? (Your health professional may be able to help you identify whether the drug was compounded.)			
Is the Product Over-the-Counter?	Yes		
Strength		If Other	
NDC number			
Did the problem stop after the person reduced the dose or stopped taking or using the product?	Yes		
Did the problem return if the person started taking or using the product again?	Doesn't Apply		
Do you still have the product in case we need to evaluate it?	No		
Returned to Manufacturer Date			

Drug Therapy 1 of 1

Expiration date			
Lot number			
Dosage Form			
Quantity	Other	If Other	1 Inhalation(s)
Frequency	4 times a day	If Other	
How was it taken or used	Respiratory (inhalation)	If Other	
Date the person first started taking or using the product	24-Jun-2018		
Date the person stopped taking or using the product	29-Jun-2018		
Therapy Duration			
Therapy Ongoing ?			

Why was the person using the product? (such as what condition was it supposed to treat) 1 of 1

Vaping instead of cigarette	
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Section C - About the Medical Device

Name of medical device	
Name of the company that makes the medical device	

Other identifying information (The model, catalog, lot, serial, or UDI number, and the expiration date, if you can locate them)

Model #	
Catalog #	
Serial #	
Lot #	
Unique Identifier (UDI) #	
Expiry Date	
Was someone operating the medical device when the problem occurred?	

For implanted medical devices ONLY (such as pacemakers, breast implants, etc.)

Date the implant was put in		Date the implant was taken out (If relevant)	
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Section D - About the Person Who Had the Problem

Person's Initials	(b) (6)
Sex	Male
Age (specify unit of time for age)	23 Year(s)
Date of Birth	
Weight	72 kg(s)
Ethnicity (Choose only one)	
Race (Check all that apply)	<input type="checkbox"/> American Indian or Alaskan Native <input type="checkbox"/> Native Hawaiian or Other Pacific Islander <input type="checkbox"/> Asian <input checked="" type="checkbox"/> White <input type="checkbox"/> Black or African American

List known medical conditions (Such as diabetes, high blood pressure, cancer, heart disease, or others)

None

Please list all allergies (such as to drugs, foods, pollen or others)

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List any other important information about the person (such as smoking, pregnancy, alcohol use, etc.)

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List all current prescription medications and medical devices being used.

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List all over-the-counter medications and any vitamins, minerals, supplements, and herbal remedies being used.

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Section E - About the Person Filling Out This Form

1 of 1

Primary?	Yes	
Reporter is Patient?		
Title		
Last name	(b) (6)	
Middle Name	(b) (6)	
First name	(b) (6)	
Number/Street		
City		
State/Province		
Country	USA	
ZIP or Postal code		
Telephone number		
Email address		
Fax		
Reporter Organization		
Department		
Reporter Speciality		
Today's date	07-Jul-2018	
Did you report this problem to the company that makes the product (the manufacturer/compounder)?	No	
If you do NOT want your identity disclosed to the manufacturer	Yes	



REPORT INFORMATION

Report Profile

Report Version	FPSR.FDA.CTP.V.V2
Report Category	Tobacco Product Report V2
Submitted	2018-10-03
FDA ICSR ID	(b) (6)
Followup by using your account	(b) (6)

Proxy Report Information (not applicable if this is not a proxy report)

Report Identifying Information

Create a name to help you find this report in the future (max length: 50 characters)	(b) (6)
Regulatory Status	Voluntary
Type of Submission	Initial
What type of report are you submitting?	Health-Related Problem associated with a tobacco product (not associated with a product problem or defect)

**Did you report this problem
somewhere else (outside
SRP)?** No

Contact Information - Sender

Organization Name	<blank>
Confirm Email	(b) (6)
First Name	(b) (6)
Last Name	(b) (6)
May the FDA share your name and contact information with the manufacturer/distributor of the tobacco product(s) described in your report?	Yes
May the FDA share your name and contact information with other federal government agencies (e.g. CDC, CPSC, FTC, TTB)?	Yes
May the FDA share your name and contact information with local or state government agencies (e.g. enforcement or public health/safety agencies)?	Yes
Did you report the problem to the manufacturer?	No
Job Title	Parent
Phone	(b) (6)
Email (If prefilled, changing this email address will not change your Login email ID)	(b) (6)
Country	United States
Street Address Line 1	(b) (6)
Street Address Line 2	<blank>
City/Town	(b) (6)
State	North Carolina
ZIP/Postal Code	(b) (6)
Sender Category	Consumer/Concerned Citizen (FdaTPR)

Consumer/Concerned Citizen Type (select all that apply) Concerned citizen

Are you the person who experienced health problems associated with a tobacco product? No

Describe your relationship to the person who experienced the health problem Parent of a teenager

Problem Summary

Problem Start Date 09/16/2018

Problem End Date <blank>

Please describe the health problem or product problem. The Attachments page will accept uploads of any records, pictures, or other information.

Our son's addiction to the Juul has been a year-long battle. Not only has it resulted in the typical adolescent nicotine-related symptoms of a brand new attention deficit struggle, lessening cognitive function, and increased impulsivity (went from high achieving "A" student to struggling "F" student) but is also causing disturbing health problems. Recently, our son had a grand mal seizure following his Juul use. While doctors are not yet trained to say for certain that the Juul is behind the problem, it is obvious to us and other parents fighting the same battle that the high nicotine content of the Juul is toxic to our children. Our son has seen a neurologist (who can't say what caused the seizure), a cardiologist (who believes his chest pains and cold sweats are connected to his Juul use), an attention deficit specialist (who can't treat his ADHD because it's caused by nicotine), a pediatrician (who can only recommend behavioral therapy to get off nicotine), a psychiatrist (who prescribed Wellbutrin to help him control the impulse to use the Juul), and a counselor (who is trying to help him stop using the Juul). The addiction is so strong that it is beyond a teenager's control. Requiring Juul to change their marketing towards teens or even punishing Juul with fines is not going to get this new generation of addicts off nicotine. Now that they're addicted, they'll find nicotine elsewhere if the Juul is not available. They can always find an older friend to purchase nicotine products. Someone needs to come up with an effective treatment to cure the addiction. As a parent fighting the battle to salvage her child's future successes, I can say the Juul problem is worse that the public realizes.

Do any of these apply to the health problem? (Select one or more) Life threatening, Emergency room visit without hospital admission

Treatment Received (select all that apply)

Healthcare Professional Visit

Please describe treatment the person received, including results of any tests (such as x-rays, lab results, or blood work). The Attachments page will accept uploads of any records, pictures, or other information.

See problem description above. In addition to the ER visit (where they confirmed that it was indeed a 6-minute long seizure and was not connected to his discontinuation of Wellbutrin), my son has been seen by a neurologist, cardiologist, pediatrician, attention deficit specialist, psychiatrist and behavioral counselor. Everyone agrees that Juul use is the root cause of the problem but no one is trained to recognize the toxicity of heavy Juul use in adolescents. This is a new problem that will catch medical professionals off guard.

How long did the health problem last (if resolved), or (if ongoing) how long has it lasted so far?

<blank>

Select Unit of Time

<blank>

What is the current status of the health problem?

Not Recovered or Unresolved

Does the health problem include a secondhand or thirdhand effect (i.e. a health problem affecting someone other than the person using the tobacco product)?

No

Affected Person

Gender

Male

Race (Select all that apply)

White

Ethnicity

Not Hispanic or Latino

Birth date of the person who experienced the health problem

(b) (6)

Age of the person when the problem occurred

15

Select Unit of Age

year(s)

Please list any known pre-existing health problems for the affected person

<blank>

Medications and Supplements

Please list the prescription medications, over-the-counter medications, vitamins, and/or supplements taken around the time of the health problem.

Wellbutrin

What are the main symptoms or health problems?

Term describing the health problem

Seizure grand mal

What are the main symptoms or health problems?

Term describing the health problem

Nicotine addiction

What are the main symptoms or health problems?

Term describing the health problem

Musculoskeletal chest pain

What are the main symptoms or health problems?

Term describing the health problem

Attention impaired

Tobacco Products

Tobacco Product Type	Electronic cigarette, electronic nicotine or vaping product(E-cigarette, e-cigars, e-hookahs, e-pipes, vape pens, hookah pens, and personal vaporizers; E-liquids, e-juice or vape juice)
Tobacco Product Subtype	E-cigarette, vape pen (or vaporizing pen), hookah pen, mod, personal vaporizer
Select all that apply to the electronic cigarette, electronic nicotine or vaping product (including electronic waterpipe)	Uses prefilled cartridge, cart, cartomizers or carto.
Select all that apply to the e-liquid, e-juice or vape juice for your electronic cigarette, electronic nicotine or vaping product	Purchased in a non-refillable disposable cartridge
Does the e-liquid, e-juice or vape juice contain any of the following? (select all that apply)	Nicotine, Flavor(s), Propylene Glycol, Other
Describe other e-liquid ingredients	Glycerol, Benzoic Acid
What type(s) of flavor(s) does the e-liquid contain? (select all that apply)	Fruit
Was the e-liquid dripped on to the atomizer or heating element?	No
Full Tobacco Product Name, including Brand and Sub-Brand (if unknown, please enter "unknown")	Juul Pods 5.0% Strength
When did the person purchase this product?	<blank>
UNIVERSAL PRODUCT CODE (UPC) from Label	<blank>
Any other identifying tobacco product codes (for example, SKU, item/catalog number, manufacturing date/ batch code)	<blank>

What is the country of manufacture of the tobacco product?	<blank>
Where is the tobacco product now?	Product was discarded
How was this product acquired?	In a Store
Do you know where the product was purchased?	No
Manufacturer Name	<blank>

Tobacco Product Packaging and Portions

Manufacturer Investigation Information

Tobacco Product Purchase Location

Tobacco Product Manufacturer Information

Tobacco Product Use Details

How was the tobacco product used?	Inhaled (smoked or vaped)
On average, how often is this tobacco product used?	Every Day

Are other substances being mixed in with the tobacco product when used?	No
Did the problem occur with first time use of the tobacco product?	No
How long has the person been using this type of tobacco product?	14
Select Unit of Measure	Month(s)
How soon after the tobacco product was last used did the health problem occur?	<blank>
Select Unit of Measure	<blank>
How long has the person been using this particular brand or label?	14
Select Unit of Measure	Month(s)
Do you think this problem was caused by a particular package or unit of this product?	No
Did the person continue to use this tobacco product after the problem occurred?	Yes
Did this same or similar health problem happen again after repeat use of the tobacco product?	No
Did the person change the product in any way before using it (for example, removing a filter from a cigarette)?	Unknown

Tobacco Product Parts

Other Products Used

Has the affected person used other tobacco products (either currently or in the past)? Yes

Other Tobacco Products

Tobacco Product Type Cigarette
Tobacco Product Subtype <blank>
Full Tobacco Product Name including Brand and Sub-Brand (if unknown, please enter "unknown") Unknown
Is the tobacco product currently being used? No

Other Tobacco Products

Tobacco Product Type Small Cigar, Little Cigar or Cigarillo
Tobacco Product Subtype Cigarillo (tipped)
Full Tobacco Product Name including Brand and Sub-Brand (if unknown, please enter "unknown") Unknown
Is the tobacco product currently being used? No
How is the tobacco product used? <blank>
On average, how often is the tobacco product used? <blank>

Other Tobacco Products

Tobacco Product Type	Electronic cigarette, electronic nicotine or vaping product(E-cigarette, e-cigars, e-hookahs, e-pipes, vape pens, hookah pens, and personal vaporizers; E-liquids, e-juice or vape juice)
Tobacco Product Subtype	E-liquid, e-juice or vape juice (purchased separately)
Full Tobacco Product Name including Brand and Sub-Brand (if unknown, please enter "unknown")	Unknown
Is the tobacco product currently being used?	No

Additional Information

Please describe anything else you think the FDA should know about this problem. Attachments may be added on the next page.

We have tried purchasing other vape devices along with low-nicotine vape juices in an attempt to ween our teen off the Juul. Those attempts backfired and the devices were destroyed. We regularly destroy any Juul products we find in our house, but in the past that has led to our son's simple acquisition of cigarettes or cigars. If Juul is going to be allowed to stay in business, they should be required to manufacture lower and Zero nicotine pods. Maybe they create rehab centers across the country to solely treat adolescent teen nicotine addiction! I see a lot in the news about the Juul epidemic and prevention but I am NOT seeing anything about how to treat the problem that is already here.

Attached Files

None



REPORT INFORMATION

Report Profile

Report Version	FPSR.FDA.CTP.V.V3
Report Category	Tobacco Product Report V3
Submitted	2019-02-06
FDA ICSR ID	(b) (6)
Followup by using your account	(b) (6)

Proxy Report Information (not applicable if this is not a proxy report)

Report Identifying Information

Create a name to help you find this report in the future (max length: 50 characters)	(b) (6)
Regulatory Status	Voluntary
Type of Submission	Initial
What type of report are you submitting?	Health Problem associated with a tobacco product (not associated with a product problem or defect)

**Did you report this problem
somewhere else (outside
SRP)?**

Yes

**Describe who the problem
was reported to**

Poison Control

Contact Information - Sender

Organization Name	(None)
Confirm Email	(b) (6)
First Name	(b) (6)
Last Name	(b)
Did you report the problem to the manufacturer?	No
Job Title	(b) (6)
Phone	(b) (6)
Email (If prefilled, changing this email address will not change your Login email ID)	(b) (6)
Country	United States
Street Address Line 1	(b) (6)
Street Address Line 2	<blank>
City/Town	(b) (6)
State	Pennsylvania
ZIP/Postal Code	(b) (6)
Sender Category	Consumer/Concerned Citizen (FdaTPR)
Consumer/Concerned Citizen Type (select all that apply)	Concerned citizen
Are you the person who experienced health problems associated with a tobacco product?	No
Describe your relationship to the person who experienced the health problem	Mother

Problem Summary

Problem Start Date 01/30/2019

Problem End Date 01/30/2019

Please describe the health problem or product problem. The Attachments page will accept uploads of any records, pictures, or other information. My daughter was on the way to school with friends and hit a JUUL a handful of times in a short period. She immediately went into a tonic/clonic seizure that lasted 2-5 minutes. the remainder of the day she had a severe headache and nausea.

Do any of these apply to the health problem? (Select one or more) None of the above

Treatment Received (select all that apply) Emergency Room Visit Without Hospital Admission

How long did the health problem last (if resolved), or (if ongoing) how long has it lasted so far? 5

Select Unit of Time minute(s)

What is the current status of the health problem? Recovered or Resolved

Affected Person

Who was affected by this tobacco problem? (Select one) (Please submit a separate report for each affected person, if possible.) User(s)

How many users were affected? 1

Gender Female

Pregnant No

Race (Select all that apply) White

Ethnicity Hispanic or Latino

Birth date of the person who experienced the problem (b) (6)

Age of the person when the problem occurred 15

Select Unit of Age year(s)

Please list any known pre-existing health problems for the affected person No current health issues or problems.

Medications and Supplements

Please list the prescription medications, over-the-counter medications, vitamins, and/or supplements taken around the time of the health problem. N/A

What are the main symptoms or health problems?

Term describing the health problem Seizure

Tobacco Products

Tobacco Product Type Electronic cigarette, electronic nicotine or vaping product(E-cigarette, e-cigars, e-hookahs, e-pipes, vape pens, hookah pens, and personal vaporizers; E-liquids, e-juice or vape juice)

Tobacco Product Subtype E-cigarette, vape pen (or vaporizing pen), hookah pen, mod, personal vaporizer

Select all that apply to the electronic cigarette, electronic nicotine or vaping product (including electronic waterpipe) Uses prefilled cartridge, cart, cartomizers or carto.

Select all that apply to the e-liquid, e-juice or vape juice for your electronic cigarette, electronic nicotine or vaping product Purchased in a non-refillable disposable cartridge

Does the e-liquid, e-juice or vape juice contain any of the Nicotine

following? (select all that apply)

Was the e-liquid dripped on to the atomizer or heating element? Unknown

Full Tobacco Product Name, including Brand and Sub-Brand (if unknown, please enter "unknown") JUUL

When did the person purchase this product? <blank>

UNIVERSAL PRODUCT CODE (UPC) from Label <blank>

Does the involved product device or package bear the "UL" symbol? <blank>

Any other identifying tobacco product codes (for example, SKU, item/catalog number, manufacturing date/ batch code) <blank>

What is the country of manufacture of the tobacco product? <blank>

Where is the tobacco product now? <blank>

How was this product acquired? <blank>

Do you know where the product was purchased? No

Manufacturer Name <blank>

Tobacco Product Packaging and Portions

Manufacturer Investigation Information

Tobacco Product Purchase Location

Tobacco Product Manufacturer Information

Tobacco Product Use Details

How was the tobacco product used?	Inhaled (smoked or vaped)
On average, how often is this tobacco product used?	Some Days
Are other substances being mixed in with the tobacco product when used?	No
Did the problem occur with first time use of the tobacco product?	No
How long has the person been using this type of tobacco product?	6
Select Unit of Measure	Month(s)
How soon after the tobacco product was last used did the problem occur?	6
Select Unit of Measure	Month(s)
How long has the person been using this particular brand or label?	6
Select Unit of Measure	Month(s)
Did the person continue to use this tobacco product after the problem occurred?	No
Did this same or similar problem happen again after repeat use of the tobacco product?	N/A - Person did not restart use

Did the person change the product in any way before using it (for example, removing a filter from a cigarette)? No

Tobacco Product Parts

Other Products Used

Has the affected person used other tobacco products (either currently or in the past)? No

Other Tobacco Products

Additional Information

Please describe anything else you think the FDA should know about this problem. Attachments may be added on the next page.

This seems to be an epidemic with our teenagers. There are no warning labels notifying consumers of the possibilities of nicotine overdoes. This is not the first incident of seizures that has been reported.

Attached Files

None

All dates displayed in the report are in EST(GMT-05:00) time zone

Company Unit	CDER-CTU	Originating Account	FAERS
Source Medium	MWO (Drug)	Source Form Type	E2B XML 3500B
Priority	Routine		
FDA Received Date	19-Mar-2019	CTU Received Date	19-Mar-2019
CTU Triage Date		CTU Data Entry Date	
Report Type	Spontaneous	Report Classification	Drug
Assign To	User		
User/Group			
Forward to Department	<input checked="" type="checkbox"/> CDER (CDER-OSE-RSS-CTU@fda.hhs.gov) (E2B)		
Case Priority	Direct		

Contact				
Case Reporter	First Name	Last Name	Email Address	Phone
<input checked="" type="checkbox"/>	(b) (6)	(b) (6)	(b) (6)	(b) (6)

Section A - About the Problem	
What kind of problem was it? (Check all that apply)	<input checked="" type="checkbox"/> Were hurt or had a bad side effect (including new or worsening symptoms) <input type="checkbox"/> Used a product incorrectly which could have or led to a problem <input type="checkbox"/> Noticed a problem with the quality of the product <input type="checkbox"/> Had problems after switching from one product maker to another maker
Date the problem occurred	16-Mar-2019
Serious	Yes
Did any of the following happen? (Check all that apply)	<input checked="" type="checkbox"/> Hospitalization - admitted or stayed longer <input type="checkbox"/> Required help to prevent permanent harm (for medical devices only) <input type="checkbox"/> Disability or health problem <input type="checkbox"/> Birth defect <input type="checkbox"/> Life-threatening <input type="checkbox"/> Death <input type="checkbox"/> Other serious/important medical incident

Tell us what happened and how it happened (Include as many details as possible)
My 20 year old daughter was vaping with a Juul. She had a grand mal seizure and was taken to the ER. She is fine now but it was the scariest thing that as ever happened to us. She has no history of seizures and the doctor feels the Juul caused it. The doctor likened it to street drugs because of unregulated pods. Please do something! My daughter says most college kids do it and my high school kids say lots of them do too. Thank you, (b) (6)

List any relevant tests or laboratory data if you know them (Include dates)
CT scan, MRI. Both were good.

Section B - About the Products		1 of 1
Suspect	Yes	
Primary?	Yes	

Product Type	Drug/Biologic		
Name of the product as it appears on the box, bottle, or package (Include as many names as you see)	Juul		
Name of the company that makes (or compounds) the product	Juul		
Is the Product Compounded? (Your health professional may be able to help you identify whether the drug was compounded.)			
Is the Product Over-the-Counter?	Yes		
Strength		If Other	
NDC number			
Did the problem stop after the person reduced the dose or stopped taking or using the product?			
Did the problem return if the person started taking or using the product again?			
Do you still have the product in case we need to evaluate it?	Yes		
Returned to Manufacturer Date			

Drug Therapy 1 of 1

Expiration date			
Lot number			
Dosage Form			
Quantity		If Other	
Frequency		If Other	
How was it taken or used		If Other	
Date the person first started taking or using the product	01-Oct-2018		
Date the person stopped taking or using the product	16-Mar-2019		
Therapy Duration			
Therapy Ongoing ?			

Why was the person using the product? (such as what condition was it supposed to treat) 1 of 1

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Section C - About the Medical Device

Name of medical device			
Name of the company that makes the medical device			

Other identifying information (The model, catalog, lot, serial, or UDI number, and the expiration date, if you can locate them)

Model #	
Catalog #	
Serial #	
Lot #	
Unique Identifier (UDI) #	
Expiry Date	
Was someone operating the medical device when the problem occurred?	

For implanted medical devices ONLY (such as pacemakers, breast implants, etc.)

Date the implant was put in		Date the implant was taken out (If relevant)	
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Section D - About the Person Who Had the Problem

Person's Initials	(b) (6)
Sex	Female
Age (specify unit of time for age)	20 Year(s)
Date of Birth	
Weight	60.75 kg(s)
Ethnicity (Choose only one)	Not Hispanic/Latino
Race (Check all that apply)	<input type="checkbox"/> American Indian or Alaskan Native <input type="checkbox"/> Native Hawaiian or Other Pacific Islander <input type="checkbox"/> Asian <input checked="" type="checkbox"/> White <input type="checkbox"/> Black or African American

List known medical conditions (Such as diabetes, high blood pressure, cancer, heart disease, or others)

HRT due to loss of ovaries at age 14.

Please list all allergies (such as to drugs, foods, pollen or others)

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List any other important information about the person (such as smoking, pregnancy, alcohol use, etc.)

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List all current prescription medications and medical devices being used.

Birth control pills

List all over-the-counter medications and any vitamins, minerals, supplements, and herbal remedies being used.

Section E - About the Person Filling Out This Form

1 of 1

Primary?	Yes	
Reporter is Patient?		
Title		
Last name	(b) (6)	
Middle Name		
First name	(b) (6)	
Number/Street	(b) (6)	
City	(b) (6)	
State/Province	TX	
Country	USA	
ZIP or Postal code	(b) (6)	
Telephone number	(b) (6)	
Email address	(b) (6)	
Fax		
Reporter Organization		
Department		
Reporter Speciality		
Today's date	19-Mar-2019	
Did you report this problem to the company that makes the product (the manufacturer/compounder)?	No	
If you do NOT want your identity disclosed to the manufacturer	No	

All dates displayed in the report are in EST(GMT-05:00) time zone

Basic Details			
Company Unit	CDER-CTU	Originating Account	FAERS
Source Medium	MWO (Drug)	Source Form Type	E2B XML 3500B
Priority	High		
FDA Received Date	20-Mar-2019	CTU Received Date	20-Mar-2019
CTU Triage Date		CTU Data Entry Date	
Report Type	Spontaneous	Report Classification	Drug
Assign To	User		
User/Group			
Forward to Department	<input checked="" type="checkbox"/> CDER (CDER-OSE-RSS-CTU@fda.hhs.gov) (E2B)		
Case Priority	Direct		

Contact				
Case Reporter	First Name	Last Name	Email Address	Phone
<input checked="" type="checkbox"/>	(b) (6)	(b) (6)	(b) (6)	(b) (6)

Section A - About the Problem	
What kind of problem was it? (Check all that apply)	<input checked="" type="checkbox"/> Were hurt or had a bad side effect (including new or worsening symptoms) <input type="checkbox"/> Used a product incorrectly which could have or led to a problem <input type="checkbox"/> Noticed a problem with the quality of the product <input type="checkbox"/> Had problems after switching from one product maker to another maker
Date the problem occurred	18-Mar-2019
Serious	Yes
Did any of the following happen? (Check all that apply)	<input checked="" type="checkbox"/> Hospitalization - admitted or stayed longer <input type="checkbox"/> Required help to prevent permanent harm (for medical devices only) <input type="checkbox"/> Disability or health problem <input type="checkbox"/> Birth defect <input checked="" type="checkbox"/> Life-threatening <input type="checkbox"/> Death <input checked="" type="checkbox"/> Other serious/important medical incident
Other serious/important medical incident	seizure

Tell us what happened and how it happened (Include as many details as possible)

My 18 year old son (b) (6) used an ecig just after waking up. Nor my wife or I knew he had ever used one. Immediately he had a seizure that lasted 4 to 8 minutes. 911, Ambulance, Emergency room, ct scan, eeg, license revoked and so on. Please help. I have the ecig, it looks to be new. I would like to have it tested by you. Please call me (b) (6) and (b) (6) Idaho (b) (6) Thank you

List any relevant tests or laboratory data if you know them (Include dates)

Section B - About the Products 1 of 1

Suspect	Yes		
Primary?	Yes		
Product Type	Drug/Biologic		
Name of the product as it appears on the box, bottle, or package (Include as many names as you see)	RENOV Zero		
Name of the company that makes (or compounds) the product	Renov?		
Is the Product Compounded? (Your health professional may be able to help you identify whether the drug was compounded.)	Yes		
Is the Product Over-the-Counter?	Yes		
Strength		If Other	
NDC number			
Did the problem stop after the person reduced the dose or stopped taking or using the product?	No		
Did the problem return if the person started taking or using the product again?	Doesn't Apply		
Do you still have the product in case we need to evaluate it?	Yes		
Returned to Manufacturer Date			

Drug Therapy 1 of 1

Expiration date			
Lot number			
Dosage Form			
Quantity		If Other	
Frequency		If Other	
How was it taken or used	Respiratory (inhalation)	If Other	
Date the person first started taking or using the product			
Date the person stopped taking or using the product			
Therapy Duration	3 Day		
Therapy Ongoing ?			

Why was the person using the product? (such as what condition was it supposed to treat) 1 of 1

18 years old and not making good choices.	
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Section C - About the Medical Device

Name of medical device	
Name of the company that makes the medical device	

Other identifying information (The model, catalog, lot, serial, or UDI number, and the expiration date, if you can locate them)

Model #	
Catalog #	
Serial #	
Lot #	
Unique Identifier (UDI) #	
Expiry Date	
Was someone operating the medical device when the problem occurred?	

For implanted medical devices ONLY (such as pacemakers, breast implants, etc.)

Date the implant was put in		Date the implant was taken out (If relevant)	
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Section D - About the Person Who Had the Problem

Person's Initials	(b) (6)
Sex	Male
Age (specify unit of time for age)	18 Year(s)
Date of Birth	
Weight	76.5 kg(s)
Ethnicity (Choose only one)	Not Hispanic/Latino
Race (Check all that apply)	<input type="checkbox"/> American Indian or Alaskan Native <input type="checkbox"/> Native Hawaiian or Other Pacific Islander <input type="checkbox"/> Asian <input checked="" type="checkbox"/> White <input type="checkbox"/> Black or African American

List known medical conditions (Such as diabetes, high blood pressure, cancer, heart disease, or others)

none

Please list all allergies (such as to drugs, foods, pollen or others)

none

List any other important information about the person (such as smoking, pregnancy, alcohol use, etc.)

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List all current prescription medications and medical devices being used.

none

List all over-the-counter medications and any vitamins, minerals, supplements, and herbal remedies being used.

vitamin d

Section E - About the Person Filling Out This Form 1 of 1

Primary?	Yes
Reporter is Patient?	
Title	
Last name	(b) (6)
Middle Name	
First name	(b) (6)
Number/Street	(b) (6)
City	(b) (6)
State/Province	(b) (6)
Country	USA
ZIP or Postal code	(b) (6)
Telephone number	(b) (6)
Email address	(b) (6)
Fax	
Reporter Organization	
Department	
Reporter Speciality	
Today's date	20-Mar-2019
Did you report this problem to the company that makes the product (the manufacturer/compounder)?	No
If you do NOT want your identity disclosed to the manufacturer	No

MEDWATCH
Individual Safety Report



...ts, product problems and
...duct use errors
Page 1 of 2
CDRH
CDER

Trace unit
sequence # (b) (6)

(b) (6)

1. Patient Identifier (b) (6)	2. Age at Time of Event or Date of Birth: 74	3. Sex <input type="checkbox"/> Female <input checked="" type="checkbox"/> Male	4. Weight 122 lb or 55.5 kg
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In confidence

Check all that apply:

1. Adverse Event Product Problem (e.g., defects/malfunctions)
 Product Use Error Problem with Different Manufacturer of Same Medicine

2. Outcomes Attributed to Adverse Event (Check all that apply)

Death: (mm/dd/yyyy) Disability or Permanent Damage
 Life-threatening (mm/dd/yyyy) Congenital Anomaly/Birth Defect
 Hospitalization - initial or prolonged Other Serious (Important Medical Events)
 Required Intervention to Prevent Permanent Impairment/Damage (Devices)

3. Date of Event (mm/dd/yyyy) 11/06/2010
4. Date of this Report (mm/dd/yyyy) 12/19/2010

(b) (6) age 74 discharged from hospital on 11/2 recovering from pneumonia. Home health nurse visited each day at home to administer antibiotic through PIC line. No problems noted during administration of meds, bp, temp, etc. Upon discharged pulmonologist gave the OK to use electronic cigarette instead of spending \$\$ on expensive nicotine patches. (b) (6) smoked for 60 years! Got the NJoy electronic cigarette and used that everyday with no visible side effects. The night of 11/6/10, went to bed 9:30 pm, wife checked on him at 10pm and he was fine. Wife went to bed at 11:30 and noticed he was mumbling something. Turned on light and found (b) (6) staring at ceiling saying "I'll be alright in a

6. Relevant Tests/Laboratory Data, including Dates

**RECEIVED
DEC 30 2010
MEDWATCH CTU**

7. Other Relevant History, including Preexisting Medical Conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, liver/kidney problems, etc.)

8. PROVIDE RELEVANT MEDICAL HISTORY
Product names and therapy dates (exclude treatment of event)
Invanz antibiotic administered by RN through PIC line

9. PRODUCT AVAILABILITY

Product Available for Evaluation? (Do not send product to FDA)

Yes No Returned to Manufacturer on: (mm/dd/yyyy)

10. SUSPECTED PRODUCTS

1. Name, Strength, Manufacturer (from product label)

#1 Name:
Strength:
Manufacturer:

#2 Name:
Strength:

2. Dose or Amount	Frequency	Route
#1 NJoy e-cig	daily	smoke/inhale
#2		

3. Dates of Use (if unknown, give duration) from to (or best estimate)

#1 11/2 to 11/6 throughout day
#2

4. Diagnosis or Reason for Use (Indication)

#1 Smoking cessation
#2

5. Event Abated After Use Stopped or Dose Reduced?

#1 Yes No Doesn't Apply
#2 Yes No Doesn't Apply

6. Event Reappeared After Reintroduction?

#1 Yes No Doesn't Apply
#2 Yes No Doesn't Apply

6. Lot #
#1
#2

7. Expiration Date
#1
#2

8. NDC # or Unique ID

1. Brand Name
NJoy electronic cigarette

2. Common Device Name
E-cig

3. Manufacturer Name, City and State
NJoy electronic cigarette Traditional Flavor NPro Style "With Nicotine"

4. Model #

5. Operator of Device
 Health Professional
 Lay User/Patient
 Other:

6. Lot #

7. Expiration Date (mm/dd/yyyy)

8. Catalog #

9. Serial #

10. Other #
UPC 10687 01379

6. If Implanted, Give Date (mm/dd/yyyy)

7. If Expired, Give Date (mm/dd/yyyy)

8. Is this a Single-use Device that was Reprocessed and Reused on a Patient?
 Yes No

9. If Yes to Item No. 8, Enter Name and Address of Reprocessor

11. Name and Address

Name: (b) (6)
Address: (b) (6)
City: (b) (6) State: FL ZIP: (b) (6)

12. Health Professional? Yes No Non-Healthcare Professional

13. Also Reported to:
 Manufacturer
 User Facility

14. If you do NOT want your identity disclosed

PLEASE TYPE OR USE BLACK INK

DSS

DEC 30 2010



(b) (6)

B.6. Describe Event or Problem (continued)

minute" Wife and daughter asked him if he was in pain, etc. while the wife called 911. Once on the line with 911, his whole body started to tremble and shake and sound like he was swallowing his tongue. He was using an oxygen concentrator at night and wife made sure that stayed in his nostrils during the "seizure". His eyes remained open during the event. Once the paramedics arrived, "seizure" was over but they rushed him to the nearest ER, put on ventilator and his BP was so low they couldn't take blood samples, so had to give him meds to raise BP. ER staff said CAT scan showed no sign of stroke. Neurologist did spinal tap--results clear. EEG showed brain activity but "slow". MRI was clear. They decided that he must have aspirated something into his lungs while laying down. He was talking to use prior to the trembling! He was ICU for 10+ days and once off the ventilator, he could not talk, eat or swallow. He knew who we were and a feeding tube inserted. After several days swallow test showed he could now eat soft foods and eventually began to talk and eat normal food. Memory was the problem. He had lost 20 years at times but we figured it was due to being in ICU for so long. At this time he is now in a skilled nursing facility/rehab, still having memory problems and may end up being in a nursing home long term because he is considered a safety risk since he cannot walk with the aid of a walker yet. His is a man who was totally ambulatory and active until 11/6. The only difference between being discharged and the "seizure" was the e-cig--had we known there were side effects, he wouldn't have

B.8. Relevant Tests/Laboratory Data, Including Dates (continued)

11/7 CAT scan, spinal tap, EEG, MRI

B.7. Other Relevant History, Including Preexisting Medical Conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.) (continued)

Heart attack 1987, another heart attack October 2010 due to pneumonia. Slight stroke 15 years ago only had weak left hand, no other problems. Smoked for 60 years. He is a white male, 74 years of age, retired due to heart condition, being treated for COPD, heart disease prior to 11/6. Smoked 1 pack of filtered cigarettes per day.

F. Concomitant Medical Products and Therapy Dates (Exclude treatment of event) (continued)

DSS

DEC 30 2010

From: [Chen, Ii-Lun](#)
To: [Rudy, Susan](#); [Chang, Nancy](#); [Durmowicz, Elizabeth](#); [Lindsey, Kimberly](#)
Subject: FW: Prayer Chain ~ February 18
Date: Wednesday, February 19, 2014 8:46:35 AM

From: Ashley, David
Sent: Wednesday, February 19, 2014 8:46 AM
To: Chen, Ii-Lun; Callahan-Lyon, Priscilla; Durmowicz, Elizabeth
Subject: FW: Prayer Chain ~ February 18

An email from my wife, edited to remove personal information. I encouraged them to go to the safety reporting portal

David L. Ashley, PhD
RADM, US Public Health Service
Director, Office of Science
Food and Drug Administration (FDA)
Center for Tobacco Products (CTP)
9200 Corporate Boulevard
Rockville, MD 20850
301-796-9339

From: (b) (6) [mailto:(b) (6)]
Sent: Wednesday, February 19, 2014 8:18 AM
To: Ashley, David
Subject: Fwd: Prayer Chain ~ February 18

Check out the description of XXXXXXXXXXXXXXXXXXXX. And they say e-cigarettes are "safe"!

(b) (6)
(b) (6)

"Do all the good you can, By all the means you can, In all the ways you can, In all the places you can, At all the times you can, To all the people you can, As long as ever you can." — John Wesley, *Letters of John Wesley*

XXXXXXXXXXXXXXXXXXXX, who was collapsed so mysteriously, is on the mend, for which XXXXXXXX and her family are profoundly grateful. The doctors finally figured out that he had nicotine poisoning. Turns out he has been trying to quit smoking, and had one of those "fake" electronic cigarettes, and something bizarre happened while he was using one, and the nicotine in it got into his nervous system and caused him to have terrible seizure like problems. Thankfully, he will be ok and XXXXXXXX appreciates all the prayers.