## I Mina'Trentai Dos Na Liheslaturan Received Bill Log Sheet

BILL NO.	SPONSOR	TITLE	DATE INTRODUCED	DATE REFERRED	CMTE REFERRED	PUBLIC HEARING DATE	DATE COMMITTEE REPORT FILED	FISCAL NOTES
264-32 (COR)	Rodriguez, Jr. Brant T. McCreadie T.C. Ada R. J. Respicio	AN ACT TO RELATIVE TO PROHIBITING THE SALE OR DISTRIBUTION OF ELECTRONIC CIGARETTES TO MINORS, BY ADDING A NEW § 6101(I) TO ARTICLE 1, AND AMENDING § 6400 OF ARTICLE 4, CHAPTER 6, TITLE 11 GUAM CODE ANNOTATED.	1/17/14 10:03 a.m.	01/17/14	Committee on Aviation, Ground Transportation, Regulatory Concerns, and Future Generations	03/12/14 9:30a.m.	05/06/14 10:08 a.m.	Fiscal Note Requested 01/28/14 Fiscal Note Waiver received 2/27/14



Chairman - Committee on Aviation, Ground Transportation, Regulatory Concerns and Future Generations I Mina' trentai Dos Na Liheslaturan Guåhan | 32nd Guam Legislature



May 5, 2014

The Honorable Judith T. Won Pat, Ed.D. Speaker I Mina'Trentai Dos na Liheslaturan Guåhan 155 Hesler Place Hagatna, Guam 96910

VIA: The Honorable Rory J. Respicio / M

Chairman

Committee on Rules, Federal, Foreign & Micronesian Affairs,

Human & Natural Resources, and Election Reform

RE: Committee Report on Bill No. 264-32 (COR)

Dear Speaker Won Pat,

Håfa adai! Transmitted herewith is the Committee Report on Bill No. 264-32 (COR) – "AN ACT RELATIVE TO PROHIBITING THE SALE OR DISTRIBUTION OF ELECTRONIC CIGARETTES TO MINORS, BY ADDING A NEW § 6101(1) TO ARTICLE 1, AND AMENDING § 6400 OF ARTICLE 4, CHAPTER 6, TITLE 11 GUAM CODE ANNOTATED."

Committee vot	es are as follows:
8	TO DO PASS
	TO NOT PASS
	TO REPORT OUT ONLY
	TO ABSTAIN
	TO PLACE IN INACTIVE FILE
Respectfully, MICHAEL F.	Q. SAN NICOLAS





Chairman - Committee on Aviation, Ground Transportation, Regulatory Concerns and Future Generations I Mina'trentai Dos Na Liheslaturan Guåhan | 32nd Guam Legislature



# **COMMITTEE REPORT**

Bill No. 264-32 (COR),

Introduced by Dennis G. Rodriguez, Jr., Brant T. McCreadie, Thomas C. Ada, Rory J. Respicio, Tina Rose Muna Barnes, V. Anthony Ada, Tommy Morrison, and Christopher M. Duenas

"AN ACT RELATIVE TO PROHIBITING THE SALE OR DISTRIBUTION OF ELECTRONIC CIGARETTES TO MINORS, BY ADDING A NEW § 6101(1) TO ARTICLE 1, AND AMENDING § 6400 OF ARTICLE 4, CHAPTER 6, TITLE 11 GUAM CODE ANNOTATED."



Chairman - Committee on Aviation, Ground Transportation, Regulatory Concerns and Future Generations I Mina' trentai Dos Na Liheslaturan Guåhan | 32nd Guam Legislature



May 5, 2014

## **MEMORANDUM**

**TO:** All Members

Committee on Aviation, Ground Transportation, Regulatory Concerns and Future Generations

RE: Committee Report on Bill No. 264-32 (COR)

Håfa adai! Transmitted herewith for your consideration is the Committee Report on Bill No. 264-32 (COR) – "AN ACT RELATIVE TO PROHIBITING THE SALE OR DISTRIBUTION OF ELECTRONIC CIGARETTES TO MINORS, BY ADDING A NEW § 6101(1) TO ARTICLE 1, AND AMENDING § 6400 OF ARTICLE 4, CHAPTER 6, TITLE 11 GUAM CODE ANNOTATED."

This report includes the following:

- Committee Voting Sheet
- Report Digest
- Copy of Bill No. 264-32 (COR)
- Public Hearing Sign-in Sheet
- Copy of COR Referral of Bill No. 264-32 (COR)
- Notices of Public Hearing
- Copy of the Public Hearing Agenda
- Public Testimony
- Supplemental Documents

Please take the appropriate action on the attached voting sheet. Your attention to this matter is greatly appreciated. Should you have any questions or concerns, please do not hesitate to contact my office.

Respectfully,

MICHAELF.O. SAN NICOLAS



Chairman - Committee on Aviation, Ground Transportation, Regulatory Concerns and Future Generations I Mina'trentai Dos Na Liheslaturan Guåhan | 32nd Guam Legislature



## **COMMITTEE VOTING SHEET**

Bill No. 264-32 (COR) — "AN ACT RELATIVE TO PROHIBITING THE SALE OR DISTRIBUTION OF ELECTRONIC CIGARETTES TO MINORS, BY ADDING A NEW § 6101(1) TO ARTICLE 1, AND AMENDING § 6400 OF ARTICLE 4, CHAPTER 6, TITLE 11 GUAM CODE ANNOTATED."

	SIGNATURE	TO DO PASS	TO NOT PASS	TO REPORT OUT ONLY	TO ABSTAIN	TO PLACE IN INACTIVE FILE
Senator Michael F.Q. San Nicolas Chairman	wil	×				
Senator Thomas C. Ada Vice Chairman	n					
Speaker Judith T. Won Pat, Ed.D. Member	A	/				
Vice Speaker Benjamin J.F. Cruz Member	PAC	4/5/4				
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Senator V. Anthony Ada Member		5/5				
Senator Aline A. Yamashita, Ph.D. Member	ay	那州				



Chairman - Committee on Aviation, Ground Transportation, Regulatory Concerns and Future Generations I Mina trentai Dos Na Liheslaturan Guåhan | 32nd Guam Legislature



## **COMMITTEE REPORT DIGEST**

## I. OVERVIEW

Bill No. 264-32 (COR) was introduced on January 17, 2014 by Senators Dennis G. Rodriguez, Jr., Brant T. McCreadie, Thomas C. Ada, Rory J. Respicio, Tina R. Muna Barnes, V. Anthony Ada, Tommy Morrison, and Chris M. Duenas. The bill was subsequently referred by the Committee on Rules to the Committee on Aviation, Ground Transportation, Regulatory Concerns, and Future Generations on January 17, 2014.

The Committee on Aviation, Ground Transportation, Regulatory Concerns and Future Generations convened a public hearing on March 12, 2014 at 9:31 a.m. in *I Liheslatura*'s Public Hearing Room. Among the items on the hearing agenda was Bill 264-32 (COR). The hearing was adjourned at 10:15 a.m.

## Public Notice Requirements

Public Hearing notices were disseminated via electronic mail to all senators and all main media broadcasting outlets on March 5, 2014, and again on March 10, 2014. Notice was also posted on *I Liheslatura*'s website beginning on March 5, 2014.

## **Senators Present**

Senator Michael F.Q. San Nicolas, Chairman Senator Thomas C. Ada, Vice Chairman Senator V. Anthony Ada, Committee Member Senator Dennis G. Rodriguez, Jr. Senator Frank B. Aguon, Jr. Senator Brant T. McCreadie

Senator Tommy Morrison

Senator Chris Duenas

## **Oral Testimony**

Ken Leon Guerrero
Chuck Tanner, Guam Comprehensive Cancer Control
James Gillan, Director, Department of Public Health and Social Services
Peter Cruz, Non-Communicable Disease Consortium Tobacco Control Team
Dr. Thomas Shieh
Beverly Encarnacion
Evan Diras

## Written Testimony

Dr. Felix Cabrera

Dr. Thomas Shieh

Dr. Annette M. David, Health Partners, LLC

Dr. John Ray Taitano, Guam Medical Society Cerina Mariano and Renata Bordallo, Guam Comprehensive Cancer Control

James Gillan, Director, Department of Public Health and Social Services

Peter Cruz, Non-Communicable Disease Consortium Tobacco Control Team

American Cancer Society, Cancer Action Network

Ken Leon Guerrero

## II. TESTIMONY & DISCUSSION

**Chairman Michael San Nicolas:** We will now begin public testimony on Bill 264-32. I would like to give the primary sponsor of the bill Senator Rodriguez an opportunity to make his opening statement.

Senator Dennis Rodriguez: Good morning and thank you very much, Mr. Chair, Thank you all for being here. This legislation, Bill 264-32, is an act relative to prohibiting the sell or distribution of electronic cigarettes to minors. As we all know, these electronic cigarettes, commonly known as e-cigarettes, are really unregulated here on our island. In federal law, there are few regulations currently in the books regarding e-cigarettes. The FDA is working on their regulations and their position paper as well. There are many studies that are out there, but none have really gotten to a state where it has been adopted by the FDA. There is some language that has been proffered by the FDA, and I will leave that up to the health professionals to share that with us this morning. However, when there are a lot of unknowns especially when it deals with the health of minors, for me and the co-sponsors of this legislation, it is better to gear on the side of caution to be able to protect our minors. What this bill does is essentially prohibit the sell and distribution of e-cigarettes to minors. It was meant as I worked with the stakeholders the NCB, the American Cancer Society, Public Health, Guam Fire Department, and many other stakeholders, we agreed that this would be the first of a lot of other discussions of e-cigarettes. We know now that on the plane, not only are tobacco smoking prohibited but e-cigarettes as well are prohibited on the plane. We know that a lot of studies and we have to wait and see where they stand, however, when it comes to the protection of minors this is the way we like to go and to ensure that we will protect them. Thank you very much, Mr. Chair.

Chairman San Nicolas: Thank you Senator Rodriguez. Also, to acknowledge my fellow senators who have joined us are Senators Chris Duenas, Tommy Morrison, and Tony Ada. We do have indicated testimony in favor from 3 individuals. I do have one individual who indicated oral testimony, Peter Cruz, but didn't indicate in favor or against. Is Peter Cruz here? Okay, I have five in favor and two not in favor. Let's go ahead and have the ones in favor take the table first if we may. I have Ken Leon Guerrero, Chuck Tanner, James Gillan, and Peter Cruz. I'm sorry only four. Thank you for joining us this morning. I have first on the list Mr. Ken Leon Guerrero if you can state your name first for the record.

Ken Leon Guerrero: My name is Ken Leon Guerrero. I am here to testify in favor of Bill 264. I agree in principle with the bill but I think it doesn't go far enough to protect the children of Guam. I am here to testify that there is a sense of urgency about this bill, and we need to recognize e-cigarettes for what they are. They're cigarettes. I have submitted written testimony so I'll just sum up the 20 pages so that we don't take up too much of the committee's time on this. I have seen a lot of anecdotal evidence that backs up an assertion by the CDC which did a research study and said 90% of smokers were smoking before they reached age 18. We have gone a long way to improve that here on Guam over the past decades as we have enacted smoking regulations. We have seen the changes in our community that benefited from those regulations. But what I'm seeing now is with these e-cigarettes, they're making a comeback. Because in offices where people are not allowed to smoke, you see people smoking e-cigarettes. I have even seen people at GPO sitting there in the walkway smoking e-cigarettes. But particularly, the thing that concerns me most is the children. Children are going to live forever so they don't worry about things like that. It is incumbent upon us to take advantage of the lessons we learned when we were younger and for those of you who were smoking. How many people smoked when you were young? Raise of hands. Okay, a few willing to admit it. What we know is when we were young we were going to live forever so we didn't worry about things like cigarettes back then. And what we found out later is by the time we got around to worrying about it, it was too late. The people who were smoking were probably going to fighting that battle for life. E-cigarettes are an easy way to get children, the primary target market for the smokers, because they are investing heavily in their future profits of their business. Why else will they make chocolate flavored, strawberry flavored, butterscotch flavored inhalant? If not to make it more appealing

to children. The reason why this is concerning to me is, I walk every day, and when I'm walking through the village. I'm seeing more and more children in front of the bus stops and in front of the village stores with their e-cigarettes. That's why I think this is important we enact it. Not only is the fact that it delivers nicotine is important. According to the FDA, there is a toxic cocktail of chemicals that are included in this chemical solution. One of them which I found particularly disturbing was diatholene glycol an active ingredient in anti-freeze. I documented my testimony in 2006, when over 700 people were poisoned by tainted cold medicine from China had a hint of anti-freeze for sweetener. And out of those 700 people, 123 died. I didn't want to keep throwing it in there but I'm sure you remember few years ago there was dog food and baby formula that caused thousands of children be sent to the doctor's office and emergency room when it too was sweetened with anti-freeze. So when did we think giving children and adults anti-freeze through an inhaler. One of those chemicals, can't even pronounce this one, it irritates the resprotory system and damages the liver. The next one is Benzene it irritates the lungs and air ways and can cause internal bleeding. In large enough doses can be fatal. Cadmium, one of the most toxic elements known to man. Once absorbed to the human body it accumulates through life. What we are perpetuating here with these cigarettes but it perpetuates these chemicals into the bodies our children's body. At some point in time, we as a society have to deal with it. We will be dealing with a different type of an addict. Phameldahide, lead, nickel the cocktail list goes on. In my written testimony. I wanted to testify today. E-cigarettes are cigarettes; we should treat them as cigarettes. Tax them as cigarettes. Maybe in the legislation make provisions for the advances in technology because just as we have an ecigarette that claims to be tobacco-less. It has chemicals to simulate all the good and bad things of cigarettes. There are more products coming down the road as we've seen with spice. When they tried to regulate spice out, what did they do, changed the chemicals. Now they are technically legal again. Amend the law to They're technically legal again. I think we should amend the law classifying eigarettes and cigarette type products and any nicotine or simulated nicotine delivery system to be recognized as cigarettes and treated appropriately. That concludes my verbal testimony; you've got the 20 pages of my written. Thank you.

Chairman San Nicolas: Thank you Mr. Leon Guerrero, Mr. Tanner.

**Chuck Tanner:** Hafa adai, my name is Chuck Tanner. I am the Chair for the policy and advocacy committee for the Guam Comprehensive Cancer Control Coalition and also the Non-communicable Disease Consortium. You have my written testimony. I'd just like to read it into the record.

Chairman San Nicolas: Thank you, Mr. Tanner. Director Gillan.

James Gillan: Thank you Mr. Chairman. Chuck stole my testimony. Most of the numbers I had were similar. What I want to admit, from a public health standpoint, we are way behind. We just didn't see this coming. We see now what's obvious. They're recruiting a whole new generation of addicts, finding another way to get nicotine into people's systems, and touting it as a fairly harmless way to do so. There is some discussion that we have heard in the community about it being an effective tobacco sensation tool. It is not. The American Cancer Society still doesn't recognize it as such. We don't know what's in there. We don't know what the strength is. I did it anyway. It wouldn't technically be second hand smoke. I think I have the right to tell people not to have it around me. It targets the children. We did the same thing with the alcohol argument. I think we ought to tax it as such. It's the solution in the cartridge. We find there is an association between e-cigarettes and picking up cigarettes again. This doesn't offer a safe way to deal with anything. I think it is a very clever, insidious way. There is a public interest. If you're going to do this, pay for it. The FDA promised to have regulations by October. We don't know when final regulations will come out. We haven't done any long term studies. We need to get on this quickly. Thank you for your time.

Senator San Nicolas: Thank you, Director Gillan. Mr. Peter Cruz.

Peter Cruz: Thank you Mr. Chairman. Senators, good morning. I sit before you on behalf of the Non-Communicable Disease Consortium and Tobacco Control Team in giving our full support of Bill 264. Originally known as Electronic Nicotine Delivery Systems or ENDS was banned in 1963 but resurfaced as electronic cigarettes in 2003. Its popularity in the last 11 years has brought sales over 1 billion dollars. Locally, the surge of popularity has seen several businesses rooting up to fill this demand. The recent demand of electronic cigarettes has been accompanied by misguided information that in reality has the possibility to adverse consequences to health in our health. I like to concentrate on the main ingredient in e-cigarettes is nicotine. Nicotine use disorder and nicotine induced disorder is cited. Nicotine induced disorder examines withdrawal symptoms such as depressed moods, insomnia, difficulty concentrating, frustration, anxiety, irritability, anger, restlessness, increased heart rate, and weight gain are the major symptoms one can experience. The second point I'd like to touch on is the usage of the under aged. 25% of high school students have used electronic cigarettes. The absence of regulatory monitoring has put this population in dire risk. Locally, public school drivers have witnessed the popularity and usage at bus stops and on the bus. Simply put we do not know the long term ramifications of this product. It can be as deadly as other forms of tobacco products on the market. Please pass bill 264 for a healthier Guam.

Chairman San Nicolas: Thank you Mr. Cruz. And thank you gentlemen for your testimony. Dr. Shieh.

**Dr. Thomas Shieh:** I am speaking on behalf of myself. I am in support of Bill 264. It is really quite simple. E-cigarettes are tasteful. Anybody under the age of 18 shouldn't be purchasing these products. The argument that comes into play with some of my colleagues is whether or not there is a benefit versus a risk. Which is the lesser of two evils? E-cigarettes are worse than smoking tobacco. This device can be a vehicle. These are the devices that have to go through the FDA. I want to encourage Public Health to educate the public on this product.

**Chairman San Nicolas:** Thank you Dr. Shieh. Are there any senators that have questions for Dr. Shieh? Senator Rodriguez.

**Senator Rodriguez:** Thank you very much Mr. Chair and thank you Dr. Shieh for taking time out of your busy schedule to be here. When you reference lines 7-9, the sentence is saying that the belief isn't safe for minors.

**Dr. Shieh:** The benefits are very little. If you're going to pass legislation, be consistent. The device in the future can have medical uses. The study needs more research.

**Senator Rodriguez:** I think we are on the same page.

Dr. Shieh: Alright.

**Chairman San Nicolas:** Thank you Dr. Shieh. The next panel indicated their opposition to the legislation. I have two individuals that signed up to present oral testimony. Mr. Even and Ms. Beverly, please join us.

**Beverly Encarnacion:** I am the owner of Vaporize. I am pro for not allowing minors to vape, but I am not okay with the taxation of the product. There have been a lot of studies; however, the product has changed within the past few years. The products we carry are made in U.S. labs. They are grade A products. Customers can also opt to not have nicotine.

Chairman San Nicolas: Thank you, Beverly. And Evan.

**Evan Diras:** Hello my name is Evan and I own Vape Guam. Just to let you guys know, since I opened up my doors I have always posted up "You must be 18 or over." I can speak for the rest of the other stores; we all agreed that we won't sell to minors. Although we see a lot of minors using e-cigarettes, it is beyond our control. If the parent agrees to purchase it for their child, it is out of our hands. Thank you.

**Chairman San Nicolas:** Thank you Evan. Do any of my colleagues have any questions for this panel? Senator Rodriguez.

**Senator Rodriguez:** Thank you very much, Mr. Chair. And thank you very much Evan and Beverly. I want to thank you for taking that corrective step in not selling to minors. This bill is very much needed as we said that we have seen minors vaping. This legislation addresses this issue. It not only prohibits the sale of e-cigarettes but it also prohibits its distribution to minors. I look forward to working closely with you and I consider you an important stakeholder in this as well.

Chairman San Nicolas: Any other Senators? Senator Duenas.

**Senator Duenas:** I want to join the sponsor in thanking you. I understand your view from a business standpoint. We need to protect our young people for things they don't foresee. However, as a government, we have to act responsibly as well. What happens to those tax dollars goes to taking care of our people. I just want you to be mindful and understanding that when the government is going to do this it does so in the best interest of our people.

**Senator San Nicolas:** Thank you Senator Dueñas. I would also like to join my fellow senators in thanking everyone who presented testimony here today. If there be no further individuals wishing to testify, we will have Bill 264 officially heard.

## III. FINDINGS AND RECOMMENDATIONS

The Committee on Aviation, Ground Transportation, Regulatory Concerns, and Future Generations hereby reports out Bill No. 264-32 (COR) with the recommendation To Do PASS

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## I MINA'TRENTAI DOS NA LIHESLATURAN GUÅHAN 2014 (SECOND) Regular Session

BILL No. 264-32(COR)

Introduced by:

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DENNIS G. RODRIGUEZ, Jr. 9
BRANT T. MCCREADIE
THOMAS C. ADA
RORY J. RESPICION
TINA MUNA BARNES
V. ANTHONY ADA
TOMMY MORRISON
CHRISTOPHER M. DUENAS

AN ACT TO RELATIVE TO PROHIBITING THE SALE OR DISTRIBUTION OF ELECTRONIC CIGARETTES TO MINORS, BY ADDING A NEW § 6101(1) TO ARTICLE 1, AND AMENDING § 6400 OF ARTICLE 4, CHAPTER 6, TITLE 11 GUAM CODE ANNOTATED.

## BE IT ENACTED BY THE PEOPLE OF GUAM:

Section 1. Legislative Findings and Intent. *I Liheslaturan Guåhan* finds that the increasing popularity and unregulated distribution of electronic cigarettes is resulting in its widespread utilization by the youth in our island community.

I Liheslaturan Guåhan finds that it has been clearly been scientifically determined that nicotine is a harmful and highly addictive drug, the use of which may lead to illness or premature death. It further finds that the prevalent belief that e-cigarettes are simply safe smoke cessation devices is not applicable when considered within the context of its use by a minor. Although the matter of regulation has not yet been determined by the U.S. FDA, its utilization by minors is a reverse application of a product which leads to addiction, not the cessation of tobacco product utilization. The current usage of e-cigarettes has been reported to be highly prevalent amongst Guam's middle and high school students.

A number of states, principally California, Colorado, and Maryland, have succeeded in passing legislation banning the sale of electronic cigarettes to minors. Likewise, the states of Hawaii, Iowa, and New York have pending legislation under consideration with the similar intent of banning the sale or distribution of these products to minors.

I Liheslaturan Guåhan finds that electronic cigarettes contain nicotine, which is highly addictive substance, as is similarly found in tobacco products. For the purposes of this Act, I Liheslaturan Guåhan duly notes that according to the U.S. Food and Drug Administration, "Electronic cigarettes", also known as "E-Cigarettes", are battery operated products designed to deliver nicotine, flavor and other chemicals. They turn nicotine, which is highly addictive, and other chemicals into a vapor that is inhaled by the user.

It is the intent of *I Liheslaturan Guåhan* to include, regulate and prohibit under 11 GCA Ch 6 the sale or distribution of electronic cigarettes to a minor, or possession by a minor. It is, further, the intent of *I Liheslaturan Guåhan* that prohibition pursuant to this Section *solely* pertains to minors, and *shall* not prohibit the use or possession of an electronic cigarette by a person eighteen (18) years of age or older.

It is the intent of *I Liheslaturan Guåhan* to protect Guam's youth from nicotine addiction, as well as the potentially harmful effects of chemicals present in unregulated e-cigarette devices, by prohibiting the sale or distribution of electronic cigarettes to, or use by minors. It is, further, the *intent* to accomplish this objective by regulating electronic cigarettes along with tobacco products for the purposes of the enforcement of this prohibition, which *shall* apply *solely* to minors.

- Section 2. A new subsection (l) is hereby added to § 6101 of Article 1, Chapter 6, Title 11, Guam Code Annotated, to read:
- "(1) Electronic cigarette, also known as "E-Cigarettes", are battery

  operated products designed to deliver nicotine, flavor and other chemicals. They

  turn nicotine, which is highly addictive, and other chemicals into a vapor that is

  inhaled by the user.
- (i) For the purposes of this Chapter and the prohibition pertaining

  solely to a minor pursuant to § 6400, tobacco product shall also be

  deemed to include and shall be similarly applicable to an electronic

  cigarette."
- Section 3. § 6400 of Article 4 of Chapter 6, Title 11, Guam Code Annotated, is hereby *amended*, to read:

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- "§ 6400. Sale or Distribution of Tobacco Products and Electronic Cigarettes to Minors Prohibited.
- It shall be a violation of this Chapter for any person to sell or distribute tobacco products or electronic cigarettes to minors. It shall not be a violation of this Chapter for any person to refuse to sell or distribute tobacco products or electronic cigarettes to any person whom the seller or the distributor reasonably believes to be under twenty-seven (27) years of age, and who is unable to produce acceptable photographic identification and proof that he is over the age of eighteen (18) years.
- The sale or distribution of electronic cigarettes to minors, or its possession
  by a minor, is prohibited and *shall* be regulated and enforced pursuant to this
  Chapter. Any provision of this Chapter applicable to the regulation and prohibition

of the sale or distribution of a tobacco product to a minor, or possession by a minor, shall be applicable to electronic cigarettes and shall be regulated and enforced in the same manner as a tobacco product, to include the applicability of all penalties and fines.

- (a) Vending machines selling tobacco products or electronic cigarettes shall be located so that they are accessible only to persons over the age of eighteen (18) or are under the constant, direct supervision and unobstructed line-of sight of the person authorizing the installation or placement of the tobacco or electronic cigarette vending machine upon the premises he manages or otherwise controls, or his agent or employee. Said supervising adult shall ensure that minors do not purchase tobacco products or electronic cigarettes from vending machines. A person who authorizes the installation or placement of the tobacco or electronic cigarette vending machine upon premises he manages, or otherwise controls, and who knows or should know that the tobacco or electronic cigarette vending machine will likely be used by minors, shall be liable if minors purchase tobacco products or electronic cigarettes from said machines.
- (b) A licensee or an employer may distribute tobacco products or electronic cigarettes to any employee who handles tobacco products or electronic products in the course of the commercial distribution or sale of the products. In any proceeding, for the suspension or revocation of any license, and based upon a violation of this Section, proof that the defendant licensee or his agent or employee demanded and was shown, before furnishing any tobacco product or electronic cigarette to a minor, an identification card, shall be a defense to the charges."

- Section 4: Severability. If any provision of this law or its application to any person or circumstance is found to be invalid or contrary to law, such invalidity shall not affect other provisions or applications of this law which can be given effect without the invalid provisions or application, and to this end the provisions of this law are severable.
- Section 5: Effective Date. This Act *shall* be immediately effective upon enactment.



## I Mina'Trentai Dos na Liheslaturan Guåhan

Committee on Aviation, Ground Transportation, Regulatory Concerns, and Future Generations SENATOR MICHAEL F.Q. SAN NICOLAS

## March 12, 2014

## Bill No. 264-32 (COR)

Introduced by Dennis G. Rodriguez, Brant T. McCreadie, Thomas C. Ada, Rory J. Respicio, Tina Muna Barnes, V. Anthony Ada, Tommy Morrison, and Christopher M. Duenas: "AN ACT RELATIVE TO PROHIBITING THE SALE OR DISTRIBUTION OF ELECTRONIC CIGARETTES TO MINORS, BY ADDING A NEW § 6101(1) TO ARTICLE 1, AND AMENDING § 6400 OF ARTICLE 4, CHAPTER 6, TITLE 11 GUAM CODE ANNOTATED."

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Bill No. 264-32 (COR)



## I Mina'Trentai Dos na Liheslaturan Guåhan

Committee on Aviation, Ground Transportation, Regulatory Concerns, and Future Generations SENATOR MICHAEL F.Q. SAN NICOLAS

March 12, 2014

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Bill No. 264-32 (COR) Page 2



## I Mina'Trentai Dos na Liheslaturan Guåhan

Committee on Aviation, Ground Transportation, Regulatory Concerns, and Future Generations SENATOR MICHAEL F.Q. SAN NICOLAS

March 12, 2014

Bill No. 264-32 (COR)

Introduced by Dennis G. Rodriguez, Brant T. McCreadie, Thomas C. Ada, Rory J. Respicio, Tina Muna Barnes, V. Anthony Ada, Tommy Morrison, and Christopher M. Duenas: "AN ACT RELATIVE TO PROHIBITING THE SALE OR DISTRIBUTION OF ELECTRONIC CIGARETTES TO MINORS, BY ADDING A NEW § 6101(1) TO ARTICLE 1, AND AMENDING § 6400 OF ARTICLE 4, CHAPTER 6, TITLE 11 GUAM CODE ANNOTATED."

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Bill No. 264-32 (COR) Page March 11, 2014

Honorable Michael F. Q. San Nicolas Chair, Committee on Aviation, Ground Transportation, Regulatory Concerns and Future Generations 155 Hesler St. Hagatna, GU 96910

Dear Senator San Nicolas,

My name is Dr. Felix T. Cabrera. I am an internal medicine physician at IHP Medical Group, Guam Memorial Hospital Authority and Guam Regional Medical City. I am writing this letter in support of Bill 264-32 (COR), AN ACT RELATIVE TO PROHIBITING THE SALE OR DISTRIBUTION OF ELECTRONIC CIGARETTES TO MINORS.

Thank you for accepting my written testimony. My apologies for not being available to provide this testimony in person.

E-cigarette use is becoming a hot topic of discussion through out the world as well as for the people of Guam. However, I feel there are two very separate debates that are occurring simultaneously and may be blurred by each other.

The first debate deals with regulation needs. The second deals with discussion of the medical risk and benefits as a smoking cessation tool. This bill deals with one aspect of regulation needs, therefore I will begin with this.

A recent report showed that already 1 in 5 U.S. middle school children – who have never previously smoked tobacco – have tried using e-cigarettes. If they become addicted to nicotine this way, this may be their gateway into using tobacco products.

Tobacco is arguably one of the most deadly substances known to man. Prevention is absolutely key. A vector for introducing a nicotine habit absolutely must be kept away from our youth. Therefore, this proposed ban on the sale and distribution of electronic cigarettes to minors is necessary.

Nonetheless, the use of e-cigarettes as a tool for smoking cessation in adults is still a topic that requires more study and education. It would be irresponsible (and almost unethical) to quickly disregard a potential weapon that may significantly decrease tobacco use in some people, particularly in those who desperately need it.

There have been false statements that state there is no evidence that e-cigarettes can be used as a smoking cessation tool. Major studies are certainly in their infancy but in September of 2013 a study was published in the prominent medical journal

The Lancet. It compared e-cigarettes with nicotine patches and found similar early results in smoking cessation and reduction.

Like anything else in medicine, this has to be applied under the principles of risk versus benefit. In the end, for many of my own patients who smoke heavily, I do not have a combination of medications powerful enough to prescribe them that will do more good for their overall health than if they just quit smoking.

I strongly agree with the American Cancer Society's plea to the Food and Drug Administration to offer guidance and provide proper restrictions in the manufacturing and distribution of e-cigarettes. As a corollary, the smoking cessation medication varenicline (Chantix) has its own set of risks. However, it is an FDA approved and regulated medication that requires a physician's prescription. In some people the benefits significantly outweigh the risk.

In summary, my current stance on e-cigarette use is that we need to regulate it, especially to protect our youth. This is why I support Bill 264-32 (COR). However, we need to be patient and allow our community to learn and explore this more as a possible tool for smoking cessation in those who desperately need it. Many times when cure is out of reach, reaching for harm reduction can still save lives.

Thank you so much for your time and attention to this matter.

Best Regards,

Felix T. Cabrera, MD, MT (ASCP)

Research

Original Investigation

# Electronic Cigarettes and Conventional Cigarette Use Among US Adolescents A Cross-sectional Study

Lauren M. Dutra, ScD: Stanton A. Glantz, PhD

**IMPORTANCE** Electronic cigarette (e-cigarette) use is increasing rapidly among adolescents, and e-cigarettes are currently unregulated.

OBJECTIVE To examine e-cigarette use and conventional cigarette smoking.

DESIGN, SETTING, AND PARTICIPANTS Cross-sectional analyses of survey data from a representative sample of US middle and high school students in 2011 (n = 17 353) and 2012 (n = 22 529) who completed the 2011 and 2012 National Youth Tobacco Survey.

**EXPOSURES** Ever and current e-cigarette use.

MAIN OUTCOMES AND MEASURES Experimentation with, ever, and current smoking, and smoking abstinence

RESULTS Among cigarette experimenters (≥1 puff), ever e-cigarette use was associated with higher odds of ever smoking cigarettes (≥100 cigarettes; odds ratio [OR] = 6.31; 95% CI, 5.39-7.39) and current cigarette smoking (OR = 5.96; 95% CI, 5.67-6.27). Current e-cigarette use was positively associated with ever smoking cigarettes (OR = 7.42; 95% CI, 5.63-9.79) and current cigarette smoking (OR = 7.88; 95% Ci, 6.01-10.32). In 2011, current cigarette smokers who had ever used e-cigarettes were more likely to intend to quit smoking within the next year (OR = 1.53, 95% CI, 1.03-2.28). Among experimenters with conventional cigarettes, ever use of e-cigarettes was associated with lower 30-day (OR = 0.24; 95% CI, 0.21-0.28), 6-month (OR = 0.24, 95% CI, 0.21-0.28), and 1-year (OR = 0.25, 95% CI, 0.21-0.30) abstinence from cigarettes. Current e-cigarette use was also associated with lower 30-day (OR = 0.11; 95% CI, 0.08-0.15), 6-month (OR = 0.11; 95% CI, 0.08-0.15), and 1-year (OR = 0.12; 95% CI, 0.07-0.18) abstinence. Among ever smokers of cigarettes (≥100 cigarettes), ever e-cigarette use was negatively associated with 30-day (OR = 0.61; 95% CI, 0.42-0.89), 6-month (OR = 0.53; 95% CI, 0.33-0.83), and 1-year (OR = 0.32; 95% CI, 0.18-0.56) abstinence from conventional cigarettes. Current e-cigarette use was also negatively associated with 30-day (OR = 0.35; 95% CI, 0.18-0.69), 6-month (OR = 0.30; 95% CI, 0.13-0.68), and 1-year (OR = 0.34; 95% CI, 0.13-0.87) abstinence.

CONCLUSIONS AND RELEVANCE: Use of e-cigarettes was associated with higher odds of ever or current cigarette smoking, higher odds of established smoking, higher odds of planning to quit smoking among current smokers, and, among experimenters, lower odds of abstinence from conventional cigarettes. Use of e-cigarettes does not discourage, and may encourage, conventional cigarette use among US adolescents.

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Supplemental content at jamapediatrics.com

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lectronic cigarettes (e-cigarettes) are devices that deliver a heated aerosol of nicotine in a fashion that mimics conventional cigarettes while delivering lower levels of toxins than a conventional combusted cigarette. They are being aggressively marketed using the same messages and media channels (plus the Internet) that cigarette companies used to market conventional cigarettes in the 1950s and 1960s, including on television and radio where cigarette advertising has been prohibited for more than 40 years.

In addition to these traditional media, e-cigarettes have established a strong advertising presence on the Internet, and e-cigarette companies heavily advertise their products through electronic communication. Studies have demonstrated for decades that youth exposure to cigarette advertising causes youth smoking.6 Electronic cigarettes are also sold using characterizing flavors (eg, strawberry, licorice, chocolate) that are banned in cigarettes in the United States because they appeal to youths. The 2011 and 2012 National Youth Tobacco Survey (NYTS) revealed that e-cigarette use among youths in grades 6 through 12 doubled between 2011 and 2012, from 3.3% to 6.8%.7 As with adults,799 concurrent dual use of e-cigarettes and conventional cigarettes was also high, with 76.3% of current e-cigarette users reporting concurrent use of conventional cigarettes in 2012.7 Likewise, e-cigarettes were introduced to Korea in 2007 using marketing techniques similar to those used in the United States, and use among adolescents rapidly increased: in 2011, 4.7% of Korean adolescents were using e-cigarettes, 76.7% of whom were dual users.3

The prevalence of e-cigarette use is also rising among adults in the United States. In a web-based survey, 13.3% of adults in 2010 and 6.2% in 2011 had ever used an e-cigarette. In addition, awareness of these products among adults increased from 40.9% in 2010 to 57.9% in 2011. Current cigarette smokers had significantly higher levels of ever e-cigarette use than former and never cigarette smokers in both years.

Electronic cigarettes are marketed as smoking cessation aids5,12-14 and many adult e-cigarette users cite the desire to stop smoking conventional cigarettes as their reason for using them. 8.15-17 However, the value of e-cigarettes as a cigarette substitute has been questioned because of high levels of dual use with conventional cigarettes. 3,8,9,11,18-20 In addition, 2 longitudinal population studies of adult smokers contradict claims that e-cigarettes are effective cessation aids: one (in the United States, United Kingdom, Canada, and Australia) found that ecigarette use is not associated with quitting conventional cigarettes21 and the other (in the United States) found significantly less quitting. 17 (A randomized clinical trial 22 found that e-cigarettes were not superior to nicotine patches for smoking cessation, but both interventions showed low quit rates and there was no control group of spontaneous quitters.) A crosssectional US study<sup>23</sup> also found that unsuccessful cigarette quitters were significantly more likely to have ever tried ecigarettes in comparison with individuals who had never tried to quit. Likewise, a cross-sectional study of Korean adolescents<sup>3</sup> found that they were using e-cigarettes as smoking cessation aids (odds ratio [OR] = 1.58; 95% CI, 1.39-1.79 for e-cigarette use among students who had made a quit attempt compared with those who had not) but were less likely to have quit smoking (OR = 0.10, 95% CI, 0.09-0.12).

To further understand the relationship between e-cigarette use with conventional cigarette use and quitting, this study used data from the 2011 and 2012 NYTS to examine the relationship between e-cigarette use and both conventional cigarette smoking and smoking cessation among US adolescents.

#### Methods

#### Data Source

The NYTS is a nationally representative cross-sectional sample of students from US middle and high schools (grades 6-12) located in all 50 states and the District of Columbia that was developed to inform national and state tobacco prevention and control programs.24 The 2011 sample included 18 866 students (88.0% response rate) from 178 schools (83.2% response rate), and the 2012 sample included 24 658 students (91.7% response rate) from 228 schools (80.3% response rate). The NYTS is an anonymous, self-administered, 81-item, pencil-and-paper questionnaire that includes indicators of tobacco use (including cigarettes, cigars, smokeless tobacco, kreteks, pipes, and emerging tobacco products), tobacco-related beliefs, attitudes about tobacco products, smoking cessation, exposure to secondhand smoke, ability to purchase tobacco products, and exposure to protobacco and antitobacco influences.25 It uses a 3-stage clustered probability sampling design without replacement to select primary sampling units (county, several small counties, portion of large county), schools within each primary sampling unit, and students within each school. Non-Hispanic black and Hispanic students are oversampled. Written permission to participate is obtained from parents or legal guardians.24 Institutional review board approval was waived because we used data from a deidentified public-use data set.

#### Variables

Conventional cigarette experimenters were defined as adolescents who responded yes to the question "Have you ever tried cigarette smoking, even 1 or 2 puffs?" Ever smokers of conventional cigarettes were defined as those who replied "100 or more cigarettes (5 or more packs)" to the question "About how many cigarettes have you smoked in your entire life?" Current smokers of conventional cigarettes were those who had smoked at least 100 cigarettes and smoked in the past 30 days.

In 2011, intention to quit smoking within the next year was measured among current cigarette smokers using the question "I plan to stop smoking cigarettes for good within the next...." Respondents who chose any time within the next year (7 days, 30 days, 6 months, or 1 year) were classified as intending to quit; those who responded "I do not plan to stop smoking cigarettes within the next year" were classified as not intending to quit. This question was not asked in 2012. We measured quit attempts with the question "During the past 12 months, how many times did you stop smoking for 1 day or longer because you were trying to quit smoking cigarettes for good?" Those who responded 1 or more times were consid-

Table 1. Sociodemographic Characteristics of Respondents in the 2011 and 2012 National Youth Tobacco Survey by Ever and Current Use of Electronic Cigarettes in 2011 and 2012

		2011 (n = 17 353)			2012 (n = 22 529)	
그 이 동물을 보고 하는데 그렇게 그렇		E-cigar	ette Use <sup>c</sup>		E-cigarette Use <sup>c</sup>	
Characteristic	Altb	Ever	Current	All	Ever	Current
Respandents, No. (%)		511 (3.1)	174 (1.1)		1450 (6.5)	462 (2.0)
Age, mean (SD), y	14,7 (0.1)	15.8 (0.1) <sup>d</sup>	15.3 (0.2) <sup>d</sup>	14.6 (0.1)	15.9 (0.1) <sup>d</sup>	15.7 (0.1) <sup>d</sup>
Gender, No. (%)						
Male	8544 (50.6)	296 (3.9) <sup>d</sup>	114 (1.6) <sup>a</sup>	11 093 (50,1)	863 (7.7) <sup>d</sup>	305 (2.7) <sup>d</sup>
Female	8809 (49.4)	215 (2.4)	60 (0.6)	11 436 (49.9)	587 (5.3)	157 (1.4)
Race, No. (%)						
Non-Hispanic white	6731 (56.6)	274 (3.8) <sup>d</sup>	81 (1.2)*	11 311 (54.7)	878 (7.8) <sup>d</sup>	257 (2.2) <sup>d</sup>
Non-Hispanic black	3102 (13.9)	28 (1.2)	12 (0.5)	2886 (13.5)	79 (2.8)	28 (1.1)
Other	7520 (29.5)	209 (2.8)	80 (1.0)	8332 (31.8)	493 (5.7)	177 (2.1)
Ever cigarette smoking, No. (%) <sup>f</sup>						
Ever	860 (5.6)	234 (30.8) <sup>d</sup>	80 (10.3) <sup>d</sup>	972 (4.5)	. 562 (57.1) <sup>d</sup>	237 (23.5) <sup>d</sup>
Never	16 493 (94:4)	277 (1.5)	94 (0.5)	21 557 (95.5)	888 (4.1)	225 (1.0)
Dual eyer use <sup>a</sup>	232 (1.7)			562 (2.6)		
Current cigarette smoking, No. (%)"						
Smoker	778 (5.0)	219 (31.9)°	76 (10.6) <sup>d</sup>	869 (4.0)	505 (57.2) <sup>d</sup>	230 (25.7) <sup>d</sup>
Nonsmoker	16 575 (95,0)	292 (1.6)	98 (0.6)	21 660 (96.0)	945 (4.4)	232 (1.1)
Dual current use	75 (0.5)			239 (1.0)		

Abbreviation; e-cigarette, electronic cigarette.

ered having made an attempt; those who responded "I did not try to quit during the past 12 months" were considered not having made a quit attempt.

Abstinence from conventional cigarettes for 30 days, 6 months, and 1 year was based on responses to the question "When was the last time you smoked a cigarette, even 1 or 2 puffs?" "Not in the past 30 days but in the past 6 months" was coded as 30-day abstinence, "not in the past 6 months but in the past year" as 6-month abstinence, and "1 to 4 years ago" or "5 or more years ago" as 1-year abstinence.

Ever e-cigarette users were defined as adolescents who responded "electronic cigarettes or e-cigarettes, such as Ruyan or NJOY," to the question "Which of the following tobacco products have you ever tried, even just 1 time?" Current e-cigarette users were those who responded "e-cigarettes" to the question "During the past 30 days, which of the following tobacco products did you use on at least 1 day?"

Covariates included race, gender, and age (in years, continuous). Race and ethnicity were coded based on answers to the questions "Are you Hispanic or Latino?" and "What race or races do you consider yourself to be?" (white, black, Asian, American Indian/Alaskan Native, or Native Hawaiian/Pacific Islander). Responses were collapsed into non-Hispanic white, non-Hispanic black, and other to obtain at least 20 ever ecigarette users in each category.

#### Statistical Analysis

The 92.0% of respondents (17 353 of 18 866) in 2011 and 91.4% of respondents (22 529 of 24 658) in 2012 with complete data on conventional cigarette use, e-cigarette use, and covariates were included in this analysis using SAS-callable SUDAAN (SAS version 9.3, SAS Institute, Inc; SUDAAN version 11.0.0, RTI International), which accounted for the stratified clustered sampling design of the NYTS, and Stata version 12.1 (StataCorp LP), which was used to pool the data from both years. Sampling weights were used in all analyses to adjust for nonresponse and the probability of selection and to match the sample's sociodemographic characteristics with those of US middle and high school students in 2011. <sup>24,25</sup>

The PROC CROSSTAB procedure was used for  $\chi^2$  analyses of categorical demographic variables by e-cigarette use. The PROC DESCRIPT and PROC REGRESS (generalized linear model) procedures provided means and P values for bivariate analyses of continuous and ordinal variables. All descriptive statistics and ORs were adjusted for stratification variables and weights. The PROC RLOGIST procedure was used to obtain ORs and 95% confidence intervals from multivariable logistic regression models of e-cigarette use and cigarette smoking, intention to quit, quit attempts, and abstinence from cigarettes, adjusting for demographic covariates. Because the NYTS study designs in 2011 and 2012 were essentially identical, we pooled

<sup>&</sup>lt;sup>a</sup> Respondents with missing values for e-cigarette use, cigarette smoking, and covariates are excluded.

b Percentages are by column

Percentages are by row. Ever e-cigarette use indicates having ever tried an e-cigarette, and current e-cigarette use indicates having used an e-cigarette in the past 30 days.

 $<sup>^{\</sup>circ}P \leq .01.$ 

<sup>\*</sup>P < .05.

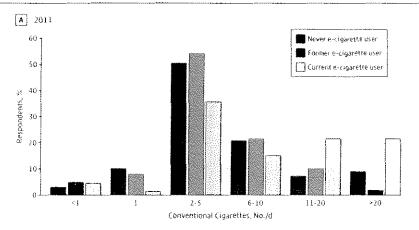
Smoked at least 100 cigarettes in lifetime.

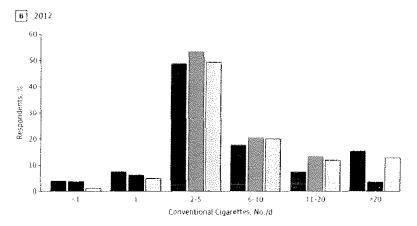
<sup>\*</sup> Percentages are of the entire sample who have ever used e-cigarettes and ever smoked conventional cigarettes.

<sup>&</sup>lt;sup>3</sup> Smoked at least 100 cigarettes in lifetime and at least a puff of a cigarette in the past 30 days.

Percentages are of the entire sample who are currently using e-cigarettes and conventional cigarettes.

Figure. Electronic Cigarette Use and Conventional Cigarette Smoking in 2011 and 2012





Current e-cigarette use in 2011 (A) and 2012 (B) was associated (P = .003 in 2011; P = .001 in 2012)with heavier smoking among conventional smokers (≥100 cigarettes in lifetime, having smoked in past 30 days). Participants were a representative sample of US middle and high school students who responded to the National Youth Tobacco Survey. Current e-cigarette users had used e-cigarettes in the past 30 days. Former e-cigarette users had tried e-cigarettes but had not used e-cigarettes in the past 30 days. Never e-cigarette users had never tried an e-cigarette. The numbers of conventional cigarettes smoked per day are on the days cigarettes were smoked during the past 30 days

adjusted ORs for e-cigarette use in 2011 and 2012 using a fixed-effects meta-analysis with the Stata metan command. As expected, there was no evidence of heterogeneity between the 2 years (median P value for heterogeneity  $\approx .32$ ; range, .09-.98).

## Results

In 2011, 3.1% of the study sample had ever tried e-cigarettes (1.7% dual ever use, 1.5% only e-cigarettes) and 1.1% were current ecigarette users (0.5% dual use, 0.6% only e-cigarettes). In 2012, 6.5% of the sample had tried e-cigarettes (2.6% dual use, 4.1% only e-cigarettes) and 2.0% were current e-cigarette users (1.0% dual use, 1.1% only e-cigarettes). Ever and current e-cigarette use varied significantly by sociodemographic characteristics (Table 1). Ever e-cigarette users were significantly more likely to be male (P < .01), white (P < .01), and older (P < .01). Ever conventional cigarette smokers (>100 cigarettes in lifetime) were significantly more likely than never smokers to have tried ecigarettes (P < .01) and to be current e-cigarette users (P < .01). Compared with nonsmokers (never and former smokers), current cigarette smokers were significantly more likely to have used e-cigarettes ( $P \le .01$ ) and to be current e-cigarette users ( $P \le .01$ ). In 2011, 45.4% of ever e-cigarette users had never been established smokers of conventional cigarettes and 49.7% of current e-cigarette users were current smokers of conventional cigarettes. In 2012, 61.2% of ever e-cigarette users had never been established smokers and 49.8% of current e-cigarette users were current cigarette smokers.

Reflecting high levels of dual use, ever and current ecigarette use was associated with very high odds of experimentation with cigarettes, ever cigarette smoking, and current cigarette smoking (eTable 1 and eTable 2 in Supplement).

Among current smokers, current e-cigarette use was associated with higher levels of cigarette smoking (P = .003 for 2011; P = .001 for 2012) (**Figure**).

In pooled analyses, among experimenters (ever smoked a puff), ever e-cigarette use was positively associated with being an established smoket ( $\pm$ 100 cigarettes; OR  $\approx$  6.31; 95% CI, 5.39-7.39) and current cigarette smoking ( $\pm$ 100 cigarettes and smoked in past 30 days; OR  $\approx$  5.96; 95% CI, 5.67-6.27). Current e-cigarette use was also associated with ever cigarette smoking (OR = 7.42; 95% CI, 5.63-9.79) and current cigarette smoking (OR = 7.88; 95% CI, 6.01-10.32) (Table 2). Table 3 shows separate analyses by year.

Use of e-cigarettes was also associated with lower odds of abstinence. Among experimenters, ever e-cigarette use associated with lower odds of 30-day (OR = 0.24; 95% CI, 0.21-

Table 2, Pooled Analysis of Ever and Current Electronic Cigarette Use and Cigarette Smoking in the 2011 and 2012 National Youth Tobacco Survey

			OR (95% CI)		
	Cigarette St	moking Status <sup>6</sup>	Ab	stinence From Cigaret	tes <sup>c</sup>
Dependent Variable	Ever	Current	30 d <sup>d</sup>	6 mo*	1 y <sup>f</sup>
Cigarette experimenters (n = 10 85	0)°				
Ever e-cigarette use <sup>n</sup>	6.31 (5.39-7.39)	5.96 (5,67-6.27)	0.24 (0.21-0.28)	0.24 (0.21-0.28)	0.25 (0.21-0.30)
Current e-cigarette use	7.42 (5.63-9.79)	7.88 (6.01-10.32)	0.11 (0.08-0.15)	0.11 (0.08-0.15)	0.12 (0.07-0.18)
Ever cigarette smokers (n = 1832)*					
Ever e-cigarette use <sup>n</sup>		ę.e.	0.61 (0.42-0.89)	0.53 (0.33-0.83)	0.32 (0.18-0.56)
Current e-cigarette use		4	0.35 (0.18-0.69)	0.30 (0.13-0.68)	0.34 (0.13-0.87)

Abbreviations: e-cigarette, efectronic cigarette; OR, odds ratio; ellipses, not applicable.

abstinence question

Table 3. Association of Electronic Cigarette Use With Ever and Current Smoking Among Adolescents Reporting Experimentation With Conventional Cigarettes in the 2011 National Youth Tobacco Survey<sup>a</sup>

		011 5169)	2012 (n = 5681)		
Dependent Variable	Ever	Current <sup>c</sup>	Ever <sup>b</sup>	Current <sup>c</sup>	
Ever e-cigarette use <sup>d</sup>					
Adjusted	7.66 (5.44-10.79)	7.43 (5.39-10.22)	5.99 (5.02-7.16)	5.61 (4.66-6.76)	
Age, y	1.33 (1.23-1.44)	1.30 (1,20-1.41)	1.24 (1.17-1.33)	1,25 (1.16-1,35)	
Race					
Non-Hispanic white	1 [Reference]	1 [Reference]	1 [Reference]	1 [Reference]	
Non-Hispanic black	0.37 (0.23-0.57)	0.43 (0.28-0.67)	0.44 (0.29-0.69)	0.47 (0.31-0.72)	
Non-Hispanic other	0.72 (0.54-0.97)	0.76 (0.57-1.01)	0.73 (0.58-0.92)	0.77 (0.60-0.99)	
Mate	1.39 (1.13-1.70)	1.44 (1.16-1.78)	1.53 (1.26-1.86)	1.44 (1.18-1.74)	
Unadjusted	8.52 (6.06-11.98)	8.31 (6.02-11.46)	6.97 (5.76-8.44)	6.52 (5.37-7.93)	
urrent e-cigarette use					
Adjusted	7.46 (4.12-13.49)	6.84 (3.95-11.84)	7.41 (5.41-10.14)	8.24 (6.04-11.23)	
Age, y	1.35 (1.25-1.46)	1.32 (1.23-1.43)	1.29 (1.22-1.37)	1.30 (1.22-1.39)	
Race					
Non-Hispanic white	1 [Reference]	1 [Reference]	1 [Reference]	1 (Reference)	
Non-Hispanic black	0.31 (0.20-0.47)	0.36 (0.24-0.55)	0.32 (0.21-0.50)	0.35 (0.23-0.53)	
Non-Hispanic other	0.67 (0.50-0,89)	0.69 (0.52-0.92)	0.61 (0.48-0.77)	0.64 (0.49-0.84)	
Male	1.38 (1.13-1.70)	1.44 (1.16-1.77)	1.55 (1.27-1.90)	1.45 (1.19-1.77)	
Unadjusted	6.84 (4.01-11.67)	6,49 (3,92-10,76)	7,52 (5,69-9,93)	8.31 (6.28-11.00)	

Abbreviations: e-cigarette, electronic cigarette; OR, odds ratio.

- <sup>4</sup> Excludes respondents with missing values for e-cigarette use, cigarette smoking, and covariates. Experimentation indicates ever tried smoking cigarettes, even 1 or 2 puffs.
- <sup>b</sup> Smoked at least 100 cigarettes in lifetime.
- Smoked at least 100 cigarettes in lifetime and at least a puff of a cigarette in the past 30 days.
- Ever tried an e-cigarette (in 2011, n = 468 {9.1% of experimenters}; in 2012, n = 1313 {23.1% of experimenters}).
- "Used an e-digarette in the past 30 days (in 2011, n = 154 (3.0% of experimenters); in 2012, n = 423 [7.4% of experimenters]).

0.28), 6-month (OR = 0.24; 95% CI, 0.21-0.28), and 1-year (OR  $\approx$  0.25; 95% CI, 0.21-0.30) abstinence from conventional cigarettes. Current e-cigarette use was also associated with lower odds of 30-day (OR = 0.11; 95% CI, 0.08-0.15), 6-month (OR = 0.11; 95% CI, 0.08-0.15), and 1-year (OR = 0.12; 95% CI, 0.07-0.18) abstinence from conventional cigarettes. **Table 4** shows analyses by year.

Among ever cigarette smokers (≥100 cigarettes), ever ecigarette use was negatively associated with 30-day (OR = 0.61; 95% CI, 0.42-0.89), 6-month (OR = 0.53; 95% CI, 0.33-0.83), and 1-year (OR = 0.32; 95% CI, 0.18-0.56) abstinence from conventional cigarettes. Current e-cigarette use was also negatively associated with 30-day (OR = 0.35; 95% CI, 0.18-0.69), 6-month (OR = 0.30; 95% CI, 0.13-0.68), and 1-year (OR = 0.34; 95% CI, 0.13-0.87) abstinence from conventional cigarettes. **Table 5** shows analyses by year.

In adjusted analyses for 2011, among current smokers, ever e-cigarette use was associated with planning to stop smoking within the next year (OR = 1.53; 95% CI, 1.03-2.28), but current e-cigarette use was not (OR = 1.34; 95% CI, 0.62-2.90). In

<sup>\*</sup>Excludes respondents with missing values for e-cigarette use, cigarette smoking, and covariates.

<sup>&</sup>lt;sup>a</sup> Ever cigarette smoking indicates having smoked at least 100 cigarettes in lifetime, and current cigarette smoking indicates having smoked at least 100 cigarettes in lifetime and at least a puff of a cigarette in the past 30 days.

Sased on answers to "When was the last time you smoked a cigarette, even 1 or 2 miffs?"

dResponded "not in the past 30 days but in the past 6 months" to the

<sup>&</sup>quot;Responded "not in the past 6 months but in the past year" to the abstinence question

Responded 11 to 4 years ago1 or 15 or more years ago1 to the abstinence

Smoked at least 1 puff of a cigarette.

h Ever thed an e-cigarette.

<sup>1</sup> Used an e-cigarette in the past 30 days.

Table 4. Ever and Current Electronic Cigarette Use by Abstinence From Smoking Conventional Cigarettes Among Adolescents Reporting Experimentation With Conventional Cigarettes in the 2011 National Youth Tobacco Survey\*

			Abstinence,	OR (95% CI) <sup>b</sup>		
		2011 (n = 5169)			2012 (n = 5681)	
Dependent Variable	30 d <sup>c</sup>	6 mo <sup>d</sup>	1 <b>y</b> °	30 d°	6 ma <sup>a</sup>	1 <b>y</b> °
Ever e-cigarette use <sup>t</sup>						
Adjusted	0.22 (0.16-0.29)	0.21 (0.16-0.28)	0.21 (0.15-0.31)	0.25 (0.21-0.29)	0.25 (0.21-0.30)	0.27 (0.22-0.33)
Age, y	0.91 (0.86-0.95)	0.94 (0.90-0.98)	0.98 (0.94-1.02)	0.91 (0.87-0.95)	0.94 (0.89-0.99)	0.95 (0.91-1.00)
Race						
Non-Hispanic white	1 [Reference]	1 [Reference]	1 [Reference]	1 [Reference]	1 [Reference]	1 [Reference]
Non-Hispanic black	1,43 (1.04-1.96)	191 (1.51-2.41)	2.18 (1.72-2.75)	1.33 (1.06-1.68)	1.98 (1.54-2.54)	2.07 (1. <del>6</del> 5-2.60)
Non-Hispanic other	1,20 (0.99-1.46)	1.40 (1.21-1.61)	1.53 (1.33-1.77)	1.09 (0.94-1.26)	1.25 (1.06-1.48)	1.36 (1.13-1.65)
Male	0.91 (0.78-1.07)	0.90 (0.76-1.06)	0.82 (0.67-1.00)	0.83 (0.73-0.93)	0.87 (0.76-1.00)	0.90 (0.77-1.05)
Unadjusted	0.20 (0.15-0.27)	0.19 (0.15-0.25)	0.19 (0.13-0.28)	0.23 (0.20-0.26)	0.22 (0.19-0.27)	0.24 (0.19-0.29)
Current e-cigarette uses						
Adjusted	0.15 (0.08-0.27)	0.15 (0.07-0.32)	0.17 (0.07-0.38)	0.10 (0.07-0.14)	0.10 (0.06-0.16)	0.10 (0.06-0.17)
Age, y	0.89 (0.85-0.93)	0.93 (0.89-0.97)	0.97 (0.93-1.01)	0.88 (0.84-0.93)	0.92 (0.87-0.96)	0.93 (0.89-0.98)
Race						
Non-Hispanic white	1 [Reference]	1 [Reference]	1 [Reference]	1 [Reference]	1 [Reference]	1 (Reference)
Non-Hispanic black	1.57 (1.16-2.12)	2.05 (1.63-2.57)	2.32 (1.84-2,92)	1.62 (1.27-2.06)	2.33 (1,79-3.03)	2.39 (1.88-3.03)
Non-Hispanic other	1.26 (1.04-1.51)	1.45 (1.27-1.66)	1.58 (1.38-1.82)	1.23 (1.05-1.44)	1.38 (1.17-1.64)	1.49 (1.22-1.81)
Male	0.91 (0.78-1.06)	0.89 (0.76-1.06)	0.81 (0.67-0.99)	0.83 (0.74-0.93)	0.87 (0.76-0.99)	0.90 (0.78-1.03)
Unadjusted	0.15 (0.08-0.27)	0.14 (0.06-0.32)	0.15 (0.07-0.35)	0.09 (0.06-0.14)	0.09 (0.06-0.15)	0.10 (0.06-0.16)

Abbreviations: e-cigarette, electronic cigarette; OR, odds ratio.

contrast, in pooled analyses, neither ever e-cigarette use (OR = 1.01; 95% CI, 0.77-1.34) nor current e-cigarette use (OR = 0.89; 95% CI, 0.61-1.30) was significantly associated with having made a quit attempt in the past 12 months after adjusting for covariates.

We also ran all analyses unadjusted by demographic variables, with little impact on the effects of e-cigarette use, indicating that the results were not due to confounding by demographic variables (Tables 3, 4, and 5).

#### Discussion

As with adults, 8-10 dual use of e-cigarettes and conventional cigarettes is high among adolescents and increasing rapidly. Adolescents who had ever experimented with cigarettes (smoked at least a puff) and used e-cigarettes were more likely to report having smoked at least 100 cigarettes and to be current smokers than adolescents who never used e-cigarettes. Thus, in combination with the observations that e-cigarette users are heavier smokers and less likely to

have stopped smoking cigarettes, these results suggest that e-cigarette use is aggravating rather than ameliorating the tobacco epidemic among youths. These results call into question claims<sup>15,26,27</sup> that e-cigarettes are effective as smoking cessation aids.

Our US results are consistent with those for Korean youths,3 with high levels of dual use in both populations. Current ecigarette users (past 30 days) were much less likely to have abstained from smoking cigarettes in the past 30 days in both populations (≥1 puff but not in past 30 days: OR = 0.10; 95% Cl, 0.09-0.12 in Korean youths vs OR = 0.15; 95% Cl, 0.08-0.28 for experimenters with cigarettes in US youths). Among current cigarette-smoking youths in Korea, there was a significant association between current e-cigarette use and attempting to quit smoking in the past 12 months (OR = 1.67; 95% Cl, 1.48-1.90), but there was not a significant association for US youths (OR = 1.20; 95% Cl, 0.65-2.23). This difference may reflect behavioral differences between the 2 countries but may also reflect the lower power in our study. The Korean sample was much larger than ours (75 643 vs 17 320 individuals, respectively) with higher prevalence of current (12.1% vs 5.0%)

<sup>\*</sup> Excludes respondents with missing values for e-cigarette use, cigarette smoking, and covariates. Experimentation indicates ever tried smoking cigarettes, even 1 or 2 puffs.

<sup>&</sup>lt;sup>6</sup> Based on answers to "When was the last time you smoked a cigarette, even 1 or 2 outfo?"

Responded "not in the past 30 days but in the past 6 months" to the abstinence question.

d Responded "not in the past 6 months but in the past year" to the abstinence question.

Responded "I to 4 years ago" or "5 or more years ago" to the abstinence question.

Ever tried an e-cigarette (in 2011, n = 468 [9.1% of experimenters]; in 2012, n = 1313 [23.1% of experimenters]).

<sup>\*</sup>Used an e-cigarette in the past 30 days (in 2011, n = 154 [3.0% of experimenters]; in 2012, n = 423 [7.4% of experimenters]).

Table 5. Ever and Current Electronic Cigarette Use by Abstinence From Smoking Conventional Cigarettes Among Ever Smokers in the 2011 National Youth Tobacco Survey\*

			Abstinence,	OR (95% CI) <sup>6</sup>		
		2011 (n = 860)	1.14	:	2012 (n = 972)	
Dependent Variable	30 đ°	6 mo <sup>d</sup>	1 y*	30 d <sup>t</sup>	6 mo <sup>d</sup>	1 y*
Ever e-cigarette use <sup>f</sup>						
Adjusted	0.57 (0.31-1.04)	0.48 (0.18-1.23)	0.40 (0.10-1.53)	0.64 (0.40-1.03)	0.54 (0.32-0.90)	0.30 (0.16-0.56)
Age, y	1.09 (0.98-1.22)	1.08 (0.93-1.26)	0.99 (0.85-1.15)	0.94 (0.80-1.10)	0.94 (0.80-1.10)	0.93 (0.77-1.12)
Race				· · · · · · · · · · · · · · · · · · ·		
Non-Hispanic White	1 [Reference]	1 [Reference]	1 [Reference]	1 [Reference]	1 [Reference]	I [Reference]
Non-Hispanic black	0.81 (0.22-3.01)	1.65 (0.38-7.07)	2.55 (0.44-14.80)	0.40 (0.16-0.99)	0.52 (0.14-1.87)	0.48 (0.10-2.23)
Non-Hispanic other	1.12 (0.72-1.74)	1:30 (0.66-2.55)	1.59 (0.60-4.19)	1.08 (0.65-1.79)	1.23 (0.62-2.45)	1.22 (0.61-2.41)
Male	0.87 (0.53-1.42)	1.49 (0.67-3.34)	1.97 (0.72-5.40)	1.53 (0.98-2.38)	1,55 (0.85-2.80)	1,74 (0,82-3,69)
Unadjusted	0.56 (0.31-1.02)	0.47 (0.19-1.18)	0.38 (0.10-1.48)	0.69 (0.44-1.09)	0.57 (0.35-0.92)	0.31 (0.17-0.58)
Current e-cigarette uses						
Adjusted	0.61 (0.23-1.64)	0.73 (0.20-2.71)	0.79 (0.14-4.42)	0.22 (0.09-0.56)	0.17 (0.06-0.49)	0.24 (0.08-0.75)
Age, y	1.08 (0.97-1.21)	1.07 (0.92-1.25)	0.99 (0.85-1.15)	0.92 (0.78-1.07)	0.91 (0.78-1.08)	0.90 (0.74-1.09)
Race						
Non-Hispanic White	1 [Reference]	1 [Reference]	1 [Reference]	1 [Reference]	1 [Reference]	1 [Reference]
Non-Hispanic black	0.91 (0.25-3.38)	1,89 (0.46-7,84)	2.96 (0.52-16.73)	0.40 (0.17-0.94)	0.56 (0.17-1.81)	0.65 (0.16-2.58)
Non-Hispanic other	1,19 (0.77-1,85)	1.40 (0.72-2.73)	1.74 (0.65-4.65)	1.16 (0.69-1.98)	1.35 (0.67-2.73)	1.38 (0.68-2.78)
Male	0.85 (0.52-1.39)	1.44 (0.65-3.15)	1.86 (0.68-5.09)	1.61 (1.04-2.49)	1.60 (0.90-2.84)	1.71 (0.82-3.57)
Unadjusted	0,56 (0.22-1.47)	0,75 (0.20-2.83)	0.89 (0.16-4.95)	0.25 (0.10-0.61)	0.20 (0.07-0.53)	0.27 (0.09-0.81)

Abbreviations: e-cigarette, electronic cigarette; OR, odds ratio.

and ever (26.3% vs 5.6%) cigarette smoking and current (4.7% vs 1.1%) and ever (9.4% vs 3.1%) e-cigarette use.

Although e-cigarettes deliver many fewer toxins and at much lower levels than conventional cigarettes, <sup>28-30</sup> they contain nicotine, a highly addictive substance, <sup>31</sup> in doses designed to mimic cigarettes. Animal models suggest that, through its effect on cholinergic pathways, nicotine may have permanent effects on the brain and behavior <sup>32,33</sup> such as dysregulation of the limbic system, which can lead to long-term difficulties with behavioral regulation, attention, memory, and motivation, among other functions. <sup>33,34</sup> The adolescent human brain may be particularly vulnerable to the effects of nicotine because it is still developing. <sup>35-37</sup>

This is a cross-sectional study, which only allows us to identify associations, not causal relationships. Our results are also limited by the lack of information about motivation for using e-cigarettes (eg., popularity, trendy, smoking cessation) and the fact that they only apply to middle and high school students, not all US youths.

In comparison with the 8.0% and 8.6% of respondents who had missing data in 2011 and 2012, respectively, and were

dropped, our analytical sample had slightly more girls (2011: 42.9% vs 49.4%, P = .007; 2012: 38.3% vs 49.9%, P < .001) and more white respondents (2011: 39.5% vs 56.6%, P < .001; 2012: 39.8% vs 54.7%, P < .001) (eTable 3 in Supplement). In 2012 only, our sample compared with students with missing data also had a lower prevalence of e-cigarette use (6.5% vs 10.2%; P = .002) and was slightly younger (mean age, 14.6 vs 14.2 years; P < .001). There were no significant differences by any of the other demographic, e-cigarette use, or cigarette smoking variables.

## Conclusions

While the cross-sectional nature of our study does not allow us to identify whether most youths are initiating smoking with conventional cigarettes and then moving on to (usually dual use of) e-cigarettes or vice versa, our results suggest that e-cigarettes are not discouraging use of conventional cigarettes. Among experimenters with conventional cigarettes, e-cigarette use is associated with established cigarette smoking and lower rates of abstinence from conventional cigarettes. The debate over

<sup>&</sup>lt;sup>a</sup> Excludes respondents with missing values for e-cigarette use, cigarette smoking, and covariates. Ever smokers are those who have smoked at least 100 cigarettes in lifetime.

b Based on answers to "When was the last time you smoked a cigarette, even 1 or 2 puffs?"

<sup>&</sup>lt;sup>6</sup> Responded "not in the past 30 days but in the past 6 months" to the abstinence question.

<sup>&</sup>lt;sup>d</sup> Responded "not in the past 6 months but in the past year" to the abstinence question,

Responded "I to 4 years ago" or "5 or more years ago" to the abstinence question.

<sup>&</sup>lt;sup>†</sup> Ever tried an e-cigarette (in 2011,  $n \approx 234$  [27.2% of ever cigarette smokers]; in 2012,  $n \approx 562$  [57.8% of ever smokers].

<sup>8</sup> Used an e-cigarette in the past 30 days (in 2011, n = 80 [9.3% of ever cigarette smokers); in 2012, 237 [24.4% of ever smokers]).

e-cigarettes<sup>2,28,31,38-40</sup> has centered on whether e-cigarettes could be useful as a harm-reduction strategy in established adult cigarette smokers. The results of our study together with those from the study in Korea<sup>3</sup> suggest that e-cigarettes may contribute to nicotine addiction and are unlikely to discourage conventional cigarette smoking among youths.

#### ARTICLE INFORMATION

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Author Contributions: Drs Dutra and Glantz had full access to all of the data in the study and take responsibility for the integrity of the data and the accuracy of the data analysis.

Study concept and design: Outra, Glantz, Analysis and interpretation of data: Dutra, Glantz, Drafting of the manuscript: Dutra, Glantz, Critical revision of the manuscript for important intellectual content: Dutra, Glantz, Statistical analysis: Dutra, Glantz, Obtained funding: Glantz

Administrative, technical, or material support: Glantz. Study supervision: Glantz.

Conflict of Interest Disclosures: None reported

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## Fwd: Urgent Guam doctor for smoking

Dr. Shieh's Clinic & Associates <doctorshieh@yahoo.com>

Tue, Mar 11, 2014 at 5:05 AM

To: michael cruz <mwcruzin@hotmail.com>, Chris Bieling <drbielingsaipan@gmail.com>,

"senatorsannicolas@gmail.com" <senatorsannicolas@gmail.com>, Pramila Sullivan <pramila008@hotmail.com>

Dear Board

Please see below. I was unable to load the YouTube on my iPhone so don't know who Public health is referring to as the doctor on Guam. When I can get to a desk top I can try to view. Any comments and support for public health on e cig, I am against any types of smokin.... Smoke is smoke.

Thomas Shieh, MD, FACOG Board Certified, ABOG www.ShiehClinic.com Office: 671 648-2229

Pager: 671 635-8360 Celi: 671 777-8360

Sent from my iPhone 5S

Begin forwarded message:

From: "Roselie V. Zabala" <roselie.zabala@dphss.guam.gov>

Date: March 10, 2014 at 11:15:00 PM GMT+10

To: Dr John TAITANO <drtaitano@gmail.com>, doctorshieh@yahoo.com, Annette David

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Subject: Fwd: PNC E Cig video

## Dear All.

Please see the link http://www.youtube.com/watch?v=\_jZ8DR2fYw0. It is so disappointing to hear that a Guam Clinician is justifying the use of e-cigarettes. It is alarming how the local radio stations are promoting e-cigarettes.

I am paging both the Guam Medical Society and the Guam Medical Association to issue their stand against the use of electronic cigarettes. There is a Public Hearing on Wednesday, March 12, 2014 at 9:30am on Bill 264-32 relative to E-Cigarettes introduced by Sen. Dennis Rodriguez.

I am attaching a Letter of Testimony written by our Tobacco Control Consultant and WHO Tobacco COntrol Adviser, Dr. Annette David.

I am also attaching an e-mail and documents courtesy of Dr. Lee Buenconsejo-Lum from JABSOM, University of Hawaii:

There is a short summary article (attached) from Medscape. I've also attached the actual study and the editorial from yesterday's Journal of the American Medical Association Pediatrics issue.

**Conclusions and Relevance** Use of e-cigarettes was associated with higher odds of ever or current cigarette smoking, higher odds of established smoking, higher odds of planning to quit smoking among current smokers, and, among experimenters, lower odds of abstinence from conventional cigarettes.

Use of e-cigarettes does not discourage, and may encourage, conventional cigarette use among US adolescents.

Electronic cigarettes (e-cigarettes) are devices that deliver a heated aerosol of nicotine in a fashion that mimics conventional cigarettes while delivering lower levels of toxins than a conventional combusted cigarette. 1-4 They are being aggressively marketed using the same messages and media channels (plus the Internet) that cigarette companies used to market conventional cigarettes in the 1950s and 1960s, 5 including on television and radio where cigarette advertising has been prohibited for more than 40 years.

In addition to these traditional media, e-cigarettes have established a strong advertising presence on the Internet, and e-cigarette companies heavily advertise their products through electronic communication. Studies have demonstrated for decades that youth exposure to cigarette advertising causes youth smoking.6 Electronic cigarettes are also sold using characterizing flavors (eg, strawberry, licorice, chocolate) that are banned in cigarettes in the United States because they appeal to youths.

The 2011 and 2012 National Youth Tobacco Survey (NYTS) revealed that e-cigarette use among youths in grades 6 through 12 doubled between 2011 and 2012, from 3.3% to 6.8%.7 As with adults 7-10 concurrent dual use of e-cigarettes and conventional cigarettes was also high, with 76.3% of current e-cigarette users reporting concurrent use of conventional cigarettes in 2012.7 Likewise, e-cigarettes were introduced to Korea in 2007 using marketing techniques similar to those used in the United States, and use among adolescents rapidly increased: in 2011, 4.7% of Korean adolescents were using e-cigarettes, 76.7% of whom were dual users.3

The prevalence of e-cigarette use is also rising among adults in the United States. In a web-based survey, 11 3.3% of adults in 2010 and 6.2% in 2011 had ever used an e-cigarette. In addition, awareness of these products among adults increased from 40.9% in 2010 to 57.9% in 2011. Current cigarette smokers had significantly higher levels of ever e-cigarette use than former and never cigarette smokers in both years.

Electronic cigarettes are marketed as smoking cessation aids 5,12-14 and many adult ecigarette users cite the desire to stop smoking conventional cigarettes as their reason for using them.8,15-17 However, the value of e-cigarettes as a cigarette substitute has been questioned because of high levels of dual use with conventional cigarettes.3,8,9,11,18-20 In

addition, 2 longitudinal population studies of adult smokers contradict claims that ecigarettes are effective cessation aids: one (in the United States, United Kingdom, Canada, and Australia) found that e-cigarette use is not associated with quitting conventional cigarettes 21 and the other (in the United States) found significantly less quitting. 17 (A randomized clinical trial 22 found that e-cigarettes were not superior to nicotine patches for smoking cessation, but both interventions showed low quit rates and there was no control group of spontaneous quitters.) A cross-sectional US study 23 also found that unsuccessful cigarette quitters were significantly more likely to have ever tried e-cigarettes in comparison with individuals who had never tried to quit. Likewise, a cross-sectional study of Korean adolescents 36 found that they were using e-cigarettes as smoking cessation aids (odds ratio [OR] = 1.58; 95% CI, 1.39-1.79 for e-cigarette use among students who had made a quit attempt compared with those who had not) but were less likely to have quit smoking (OR = 0.10; 95% CI, 0.09-0.12).

To further understand the relationship between e-cigarette use with conventional cigarette use and quitting, this study used data from the 2011 and 2012 NYTS to examine the relationship between e-cigarette use and both conventional cigarette smoking and smoking cessation among US adolescents.

Thank you.

## Roselie V. Zabala, MSW

Health Services Administrator
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**Mission Statement:** "To improve the health and quality of life in our community by eliminating health disparities; increasing access to health care; early disease detection; disease prevention and control; and promoting healthy lifestyles through policy development, implementation, surveillance and intervention; and providing social services in collaboration with community partners and stakeholders."

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To: "Roselie V. Zabala" <roselie.zabala@dphss.guam.gov>

Cc: "Elizabeth guerrero" <elizabeth.guerrero@dphss.guam.gov>

Sent: Monday, March 10, 2014 4:59:49 PM

Subject: Fwd: PNC E Cig video

ms rose, please watch this MD's statement regarding e-cigarettes.

Christopher Surla | Health Educator | Tobacco Prevention and Control Program | Department of Public Health and Social Services | Bureau of Community Health Services | tel: 671.735.7334 | fax: 671.735.7500

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Sent: Monday, March 10, 2014 4:54:18 PM

Subject: PNC E Cig video

http://www.youtube.com/watch?v=\_jZ8DR2fYw0

Christopher Surla | Health Educator | Tobacco Prevention and Control Program | Department of Public Health and Social Services | Bureau of Community Health Services | tel: 671.735.7334 | fax: 671.735.7500

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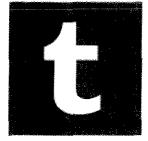
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www.medscape.com

# e-Cigs No Deterrent, Likely Contributor, to Teen Smoking

Caroline Cassels March 06, 2014

Far from claims that electronic cigarettes (e-cigarettes) may help curb conventional cigarette use in youth, new research suggests that these increasingly popular products may actually contribute to nicotine addiction.

A large, cross-sectional study of US middle school and high school students showed that current e-cigarette smokers were more than 7 times more likely to be current cigarette smokers than their counterparts who had not used e-cigarettes.

"The debate over e-cigarettes has centered on whether e-cigarettes could be useful as a harm-reduction strategy in established adult cigarette smokers. The results of our study...suggest that e-cigarettes may contribute to nicotine addiction and are unlikely to discourage conventional cigarette smoking among youths," authors Lauren M. Dutra, ScD, and Stanton A. Glantz, PhD, both from the Center for Tobacco Research and Education, University of California, San Francisco, write.

The study was published online March 6 in JAMA Pediatrics.

#### Use Doubles

Battery-operated products, e-cigarettes vaporize nicotine, flavor, and other chemicals that are then inhaled by the user. Currently unregulated, these products are aggressively marketed as a "safe" alternative to conventional tobacco products and as smoking cessation aids.

However, previous research showing high rates of dual use of e-cigarettes and conventional cigarettes brings into question the products' efficacy as cigarette substitutes and/or smoking cessation aids.

To gain a better understanding of the relationship between e-cigarette use and conventional cigarette use and smoking cessation, the investigators examined survey data from middle school and high school students in 2011 (n = 17,353) and 2012 (n = 22,529) who completed the National Youth Tobacco Survey.

The investigators found that in 2011, 3.1% of adolescents had ever tried e-cigarettes at least once (1.7% use with cigarettes, 1.5% with only e-cigarettes). Results also showed that 1.1% were current e-cigarette users (0.5% use with cigarettes, 0.6% with only e-cigarettes).

By 2012, 6.5% of adolescents had tried e-cigarettes (1% use with cigarettes, 1.1% with only e-cigarettes).

The investigators report that among cigarette experimenters (≥1 puff), ever using e-cigarettes was associated with higher odds of ever smoking cigarettes (≥100 cigarettes; odds ratio [OR] = 6.31; 95% confidence interval [CI], 5.39 - 7.39) and currently using e-cigarettes (OR, 5.96; 95% CI, 5.67 - 6.27).

They also report that current e-cigarette use was positively associated with ever smoking cigarettes (OR = 7.42; 95% CI, 5.63 - 9.79) and current cigarette smoking (OR = 7.88; 95% CI, 6.01 - 10.32).

The results also showed that in 2011, current cigarette smokers who had ever used e-cigarettes were more likely to intend to quit smoking within the next year. However, e-cigarettes were associated with lower abstinence rates from conventional cigarettes.

"Use of e-cigarettes was associated with higher odds of ever or current cigarette smoking, higher odds of established smoking, higher odds of planning to quit smoking among current smokers, and, among experimenters, lower odds of abstinence from conventional cigarettes. Use of e-cigarettes does not discourage, and may encourage, conventional

cigarette use among US adolescents," the investigators conclude.

## **Need for Quick Action**

In an accompanying editorial, Frank J. Chaloupka, PhD, University of Illinois in Chicago, notes that the use of ecigarettes, which are also known as electronic nicotine delivery systems (ENDS), is projected by some analysts to surpass sales of traditional cigarettes in the not-too-distant future.

The current study, he writes, "highlights some of the concerns about the potential public health harms" from these products, including the doubling of ever use among teenagers between 2011 and 2012 and the link between the use of these products and reduced likelihood of abstinence from conventional cigarettes.

"While much remains to be learned about the public health benefits and/or consequences of ENDS use, their exponential growth in recent years, including their rapid uptake among youths, makes it clear that policy makers need to act quickly. Adopting the right mix of policies will be critical to minimizing potential risks to public health while maximizing the potential benefits," Dr. Chaloupka writes.

The authors and Dr. Chaloupka report no relevant financial relationships.

JAMA Pediatr. Published online March 6, 2014. Abstract, Editorial

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Cite this article: e-Cigs No Deterrent, Likely Contributor, to Teen Smoking. Medscape. Mar 06, 2014.



### Tobacco Control Policy and Electronic Cigarettes

Frank J. Chaloupka, PhD

During the past few years, the use of electronic nicotine delivery systems (ENDS), commonly known as electronic cigarettes (e-cigarettes), has risen rapidly in the United States, with

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some analysts suggesting that ENDS sales could surpass sales of traditional cigarettes in the not-too-distant fu-

ture. This rapid rise has stimulated a vigorous debate in the tobacco control community over the potential public health impact of ENDS and about how best to regulate them. The article by Dutra and Glantz' highlights some of the concerns about the potential public health harms from ENDS, documenting the more than doubling of ever use among US teenagers between 2011 and 2012 and the associations of ENDS use with more established smoking and, among experimenters, reduced likelihood of abstinence from conventional cigarettes. At the same time, their article highlights the potential promise of ENDS, with their use associated with greater interest in quitting among current young smokers. The same phenomena are seen among adult smokers, with awareness and ever use of ENDS rising sharply from 2010 to 2011 and high rates of dual use among users of ENDS and conventional cigarettes, while many users report using ENDS in an effort to quit smoking.2 To date, however, the empirical evidence on the effectiveness of ENDS use in promoting smoking cessation is mixed at best, with some studies finding either no association or a negative association between ENDS use and quitting and others suggesting effectiveness equivalent to that of nicotine patches.3.4

As ENDS use has grown in the United States, federal, state, and local governments have struggled with how to treat ENDS under existing tobacco control policies and/or with developing and implementing new policies. In part, this struggle reflects the desire to maximize the use of ENDS as a smoking cessation tool, while at the same time preventing youths from starting with ENDS and moving on to conventional cigarettes. While not harmless, moving current smokers from cigarettes to ENDS would almost certainly lead to significant reductions in the health and economic consequences of smoking.5 However, the high rates of use of both ENDS and conventional cigarettes among current ENDS users suggest that many are using them as a way to satisfy their nicotine addiction in venues where smoking is not allowed rather than as a means to quit smoking entirely, raising concerns that the public health impact of ENDS could be minimal.

The inclusion of ENDS under some tobacco control policies seems clearly appropriate. The rising rates of ENDS use among youths and concerns that ENDS will become a gateway to conventional cigarettes provide a strong rationale for minimum purchase age laws, requirements that ENDS be

placed behind the counter, and other policies aimed at preventing youths' access to them. As of mid-November 2013, youth access laws in 22 states included ENDS (Camille K. Gourdet, JD, MA, Jamie F. Chriqui, PhD, and F.J.C., unpublished data, November 2013), while local policies in many jurisdictions do the same. Similarly, given the growing evidence that the vapors produced by ENDS contain nicotine, benzene, cadmium, formaldehyde, isoprene, toluene, and other potentially harmful chemicals, 6 including ENDS use under state and local policies prohibiting smoking in workplaces, restaurants, bars, and other public places would be an important step in protecting nonusers from exposure to secondhand vapors. In mid-November 2013, smoke-free air policies in 11 states explicitly addressed ENDS use (Camille K. Gourdet, JD, MA, Jamie F. Chriqui, PhD, and F.J.C., unpublished data, November 2013), while local policies in 108 communities did the same in early January 2014.7

Bringing ENDS under the jurisdiction of the US Food and Drug Administration (FDA) over tobacco products will be another key step. This would subject them to the FDA's existing regulations on cigarettes, including its efforts to reduce youth access and its ban on the sale of flavored products, which would help reduce the appeal of ENDS to youths. At the same time, it would open the possibility of future FDA regulations that would restrict ENDS marketing, regulate labeling, require disclosure of ingredients, establish product standards, and more. The FDA's past efforts to assert jurisdiction over ENDS have been unsuccessful, but the agency is soon expected to release a proposed deeming rule that would encompass the variety of other tobacco products currently not subject to FDA regulation, including ENDS. Constraining ENDS marketing and including them under comprehensive smoke-free policies would help ensure that the strong social norms against smoking that have developed in the 50 years since the release of the first US Surgeon General's report on the health consequences of smoking would not be eroded, as may be happening in the wake of extensive ENDS advertising on television, radio, and billboards and in newspapers and magazines as well as widespread ENDS use in venues where cigarette smoking is prohibited.

Less clear is whether ENDS should be taxed and, if they are, at what level to tax them. Extensive research shows that a significant increase in tobacco taxes that raises tobacco product prices is the single most effective policy for reducing tobacco use and shows that use among young people is particularly sensitive to price, <sup>8</sup> while new research shows that ENDS sales are highly responsive to changes in their prices (Jidong Huang, PhD, John A. Tauras, PhD, and F.J.C., unpublished data, December 2013). Additionally, many ENDS users report that the low cost of ENDS relative to cigarettes is a key reason for use

(Maansi Bansal-Travers, PhD, Andrew Hyland, PhD, Cheryl Rivard, MPH, F.J.C., Jidong Huang, PhD, and Dianne Barker, MHS, unpublished data, January 2014). This implies that taxing ENDS at rates comparable to cigarettes would be highly effective in deterring youths' initiation of ENDS use but at the same time would discourage many current smokers from switching to ENDS. At the other extreme, failing to levy a tax on ENDS would keep their prices relatively low, which could lead to youths' experimentation with ENDS and subsequent progression to conventional cigarette smoking. This suggests that governments that decide to levy taxes on ENDS should at the same time adopt significant increases in their other tobacco taxes so that the prices of cigarettes and other combusted tobacco products rise relative to prices for ENDS. Such a policy would have

the benefit of deterring initiation of all tobacco use, including ENDS use, among young people while increasing cessation among current tobacco users, at least in part by encouraging substitution to ENDS. To date, only Minnesota levies an excise tax on ENDS, with similar taxes under consideration in several others states (Camille K. Gourdet, JD, MA, Jamie F. Chriqui, PhD, and F.J.C., unpublished data, November 2013).

While much remains to be learned about the public health benefits and/or consequences of ENDS use, their exponential growth in recent years, including their rapid uptake among youths, makes it clear that policy makers need to act quickly. Adopting the right mix of policies will be critical to minimizing potential risks to public health while maximizing the potential benefits.

#### ARTICLE INFORMATION

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Conflict of Interest Disclosures: None reported.

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March 10, 2014

Honorable Senator Dennis G. Rodrigues, Jr. 32<sup>nd</sup> Guam Legislature 176 Serenu Avenue Suite 107 Tamuning, Guam 96913

RE: Bill No. 264-32 (COR) – An Act relative to prohibiting the sale or distribution of electronic cigarettes to minors

Dear Senator Rodriguez:

Hafa adai!

As physicians and health professionals who actively advocated for Guam's previous health-related policies, we are writing you once more to express our strong support for Bill 264-32 (COR) prohibiting the sales and distribution of electronic cigarettes to minors.

Electronic cigarettes, also known as e-cigarettes or electronic nicotine delivery systems (ENDS) are unregulated products, and the evidence regarding their impact on health is slowly emerging. What is known gives cause for serious concern.

- E-cigarette cartridges generally contain up to 20 mg of nicotine<sup>1</sup>, and nicotine is one of the most addictive substances known to man. Even when e-cigarettes are labeled as having "no nicotine," tests by the US Food and Drug Administration showed detectable levels of nicotine in all but 1 sample."
- Analyses conducted by the US Food and Drug Administration (FDA) from 2 leading brands of e-cigarettes found diethylene glycol and nitrosamines in e-cigarette cartridges.<sup>6</sup> These are highly toxic substances. Diethylene glycol is a potentially lethal human toxin, which has been implicated in numerous mass poisoning incidents worldwide; because of its adverse effects on humans, diethylene glycol is not allowed for use in food and drugs. Nitrosamines are established human carcinogens.
- There is growing evidence that the vapors produced by e-cigarettes contain nicotine, benzene, cadmium, formaldehyde, isoprene, toluene, and other potentially harmful chemicals. Thus, "second-hand e-cigarette vapor" may be as dangerous as second hand smoke.
- A very recent study published in the Journal of the American Medial Association Pediatrics last March 6, 2014 demonstrated that use of e-cigarettes among teens in the US has doubled from 3.1% in 2011 to 6.5% in 2012. Moreover, teens who reported ever using e-cigarettes were more likely to be current smokers and less likely to be successful in their attempts to quit tobacco use. The study authors concluded ""Use of e-cigarettes was associated with higher odds of ever or current cigarette smoking, higher odds of established smoking, higher odds of

planning to quit smoking among current smokers, and, among experimenters, lower odds of abstinence from conventional cigarettes. Use of e-cigarettes does not discourage, and may encourage, conventional cigarette use among US adolescents."

 In Guam, we are seeing increasing use of e-cigarettes by our young people. Our community-based participatory research project mapping tobacco advertising at the point-of-sale demonstrated widespread advertising of e-cigarettes, several of which come in candy and fruit flavors which appeal to youth.

Because the safety of e-cigarettes is under question, and the evidence base for its adverse health impact is growing, countries and US States and local jurisdictions have begun passing legislation to restrict its use.

- As of mid-November 2013, youth access laws in 22 states included e-cigarettes (Camille K.Gourdet, JD,MA, JamieF. Chriqui,PhD,andF.J.C., unpublisheddata, November 2013). California, Minnesota, New Hampshire, New Jersey, New York, Kansas, Vermont, and Utah have prohibited the sale of e-cigarette to minors since March 2011.<sup>vi</sup>
- Additionally, e-cigarettes are being added to smoking bans in public places. Nationally, several state and local governments, including New Jersey<sup>vii</sup> and King County, viii Washington, have included or are in the process of adding e-cigarettes to their smoking bans. Furthermore, the U.S. Department of Transportation has proposed banning the use of e-cigarettes on planes.<sup>ix</sup> Already, several airlines have prohibited smoking e-cigarettes on their aircrafts on their own initiative.<sup>x</sup>, xi
- Locally, the Guam Community College and the Department of Public Health and Social Services ban e-cigarette use within their premises.
- Globally, several countries, including Australia, China, and Brazil have banned the sale and marketing of e-cigarettes.<sup>xi</sup>

Currently, e-cigarettes remain unregulated by federal law. In Guam, e-cigarettes can be sold without restrictions, even to children. However, the mounting evidence highlighting the negative health effects of these products requires action to protect our youth. Thus, passing **Bill No. 264-32 (COR)** is a sound and urgently needed law to safeguard the health of Guam's youth.

We strongly support enacting this Bill into law. We also recommend that your office consider incorporating e-cigarettes into the Natasha Protection Act, to minimize the harmful effects of "second hand vapor."

Thank you, once again, for taking a health champion's role to ensure a healthy future for our island!

Sincerely,

Annette M. David Senior Partner Health Partners, L.L.C.

aw

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Websife: http://www.healthpartnersguam.com

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### Letter in Support of Bill 264-32

Anjaneen Taitano <aptaitano@gmail.com>

Fri, Jan 31, 2014 at 10:57 AM

To: senatorsannicolas@gmail.com

Cc: theguammedicalsociety@gmail.com

1/31/2014

Hafa Adai Senator San Nicolas,

Please find attached herewith Dr. John Ray Taitano's Letter in Support of Bill 264-32. Any questions or concerns can be directed to telephone: (671) 300-0843 or Email: theguammedicalsociety@gmail.com .

Regards,

A.P. Taitano, RN for

Dr. John Ray Taitano





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2/1/2014

Honorable Michael F.Q. San Nicolas Committee on Aviation, Ground Transportation, Regulatory Concerns, and Future Generations 32<sup>nd</sup> Guam Legislature 155 Hesler St. Hagåtña, Guam 96910

RE: Letter in Support of Bill 264-32 (An Act Relative to Prohibiting the Sale or Distribution of Electronic Cigarettes to Minors, by Adding a New § 6101(1), to Article 1, and Amending § 6400 of Article 4, Chapter 6, Title 11, Guam Code Annotated).

Dear Senator San Nicolas,

*Hafa Adai!* As a member of the Guam Comprehensive Cancer Control Coalition (Cancer Coalition) and resident of Guam, I strongly support Bill 264-32 (An Act Relative to Prohibiting the Sale or Distribution of Electronic Cigarettes to Minors, by Adding a New § 6101(1), to Article 1, and Amending § 6400 of Article 4, Chapter 6, Title 11, Guam Code Annotated).

The use of electronic cigarettes or electronic nicotine delivery systems has steadily increased in the past couple of years. Its popularity can be attributed to how this product is being marketed in our community: that it is a better alternative to tobacco smoking, that it is safe, and that it is an effective way to quit smoking.

According to the U.S. Centers for Disease Control and Prevention, the use of electronic cigarettes among U.S. middle school and high school students doubled during 2011-2012. In 2012, an estimated 1.78 million students reported having ever used electronic cigarettes. One hundred sixty thousand (160,000) of these students who used electronic cigarettes had never used conventional cigarettes. The numbers are alarming since the impact of using electronic cigarettes on public health is still uncertain. However, a growing body of knowledge can already be shared.

The World Health Organization has stated that the safety of these products and its efficacy to help people stop smoking has not been scientifically demonstrated. Electronic cigarettes contain nicotine which is a chemical that has been proven to be harmful to children, nursing mothers, pregnant women, the elderly, and people with heart conditions. In fact, a nicotine cartridge of 24mg may cause acute nicotine poisoning when accidentally swallowed by a child. Nonsmokers of tobacco products may be at risk for addiction to smoking electronic cigarettes.

In addition, although electronic cigarettes do not generate smoke via burning tobacco, this does not mean it is safer to use than conventional cigarettes. Chemicals in electronic cigarettes have not been fully disclosed and there has been no adequate information on their emission. However, the American Cancer Society has stated that in initial lab tests, the FDA found carcinogens (chemicals that cause cancer) and other toxic chemicals in detectable levels from a couple of electronic cigarette brands and cartridges.

I believe that prohibiting minors from purchasing electronic cigarettes will discourage our youth from developing poor health behaviors and will limit their exposure to a new product whose impact on health is still unknown. We commend you for making the right choice for our people and we encourage your colleagues to do the same. Please act now and pass Bill 264.

Thank you,

John Ray Taitano, MD, MSS, FACP

President

Guam Medical Society



January 27, 2014

Honorable Michael F.Q. San Nicolas Committee on Aviation, Ground Transportation, Regulatory Concerns, and Future Generations 32<sup>nd</sup> Guam Legislature 155 Hesler St. Hagātña, Guam 96910

Dear Senator San Nicolas,

Thank you for sponsoring Bill 264-32 (An Act Relative to Prohibiting the Sale or Distribution of Electronic Cigarettes to Minors, by Adding a New § 6101(1), to Article 1, and Amending § 6400 of Article 4, Chapter 6, Title 11, Guam Code Annotated).

The use of electronic cigarettes or electronic nicotine delivery systems has steadily increased in the past couple of years. Its popularity can be attributed to how this product is being marketed in our community: that it is a better alternative to tobacco smoking, that it is safe, and that it is an effective way to quit smoking.

According to the U.S. Centers for Disease Control and Prevention, the use of electronic cigarettes among U.S. middle school and high school students doubled during 2011-2012. In 2012, an estimated 1.78 million students reported having ever used electronic cigarettes. One hundred sixty thousand (160,000) of these students who used electronic cigarettes had never used conventional cigarettes. The numbers are alarming since the impact of using electronic cigarettes on public health is still uncertain. However, a growing body of knowledge can already be shared.

The World Health Organization has stated that the safety of these products and its efficacy to help people stop smoking has not been scientifically demonstrated. Electronic cigarettes contain nicotine which is a chemical that has been proven to be harmful to children, nursing mothers, pregnant women, the elderly, and people with heart conditions. In fact, a nicotine cartridge of 24mg may cause acute nicotine poisoning when accidentally swallowed by a child. Nonsmokers of tobacco products may be at risk for addiction to smoking electronic cigarettes.

In addition, although electronic cigarettes do not generate smoke via burning tobacco, this does not mean it is safer to use than conventional cigarettes. Chemicals in electronic cigarettes have not been fully disclosed and there has been no adequate information on their emission. However, the American Cancer Society has stated that in Initial lab tests, the FDA found carcinogens (chemicals that cause cancer) and other toxic chemicals in detectable levels from a couple of electronic cigarette brands and cartridges.

The Guam Comprehensive Cancer Control Coalition supports Bill 264. We believe that prohibiting minors from purchasing electronic cigarettes will discourage our youth from developing poor health behaviors and will limit their exposure to a new product whose impact on health is still unknown. We commend you for making the right choice for our people and we encourage your colleagues to do the same. Please act now and pass Bill 264.

Sincerely.

Cefina Y. Mariano

Char

Renata Bordallo Vice-Chair

Heret Bridge



#### Bill 264-32 Re E-smoking

James Gillan <james.gillan@dphss.guam.gov>

Thu, Feb 13, 2014 at 10:54 AM

To: senatorsannicolas@gmail.com, roryforguam@gmail.com, "Dennis G. Rodriguez, Jr." <senator@toduguam.com>, "Benjamin J.F. Cruz" <senator@senatorbjcruz.com>, senatortonyada@guamlegislature.com, aline4families@gmail.com

Dear Senator San Nicolas:

I know you all have been quite bust lately, but I am hopeful that your Committee will address this bill in a hearing soon. I am requesting that you not only restrict the sale of these Electronic Nicotine Delivery Systems (ENDS) to those over 21 years of age, but also tax them and their cartridges as tobacco products. Additionally, I would hope that at a minimum these ENDS would not be allowed to be used in Government Buildings.

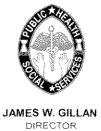
Respectfully,

James W. Gillan Director, DPHSS

#### **GOVERNMENT OF GUAM**



## DEPARTMENT OF PUBLIC HEALTH AND SOCIAL SERVICES DIPATTAMENTON SALUT PUPBLEKO YAN SETBISION SUSIAT



RAY TENORIO
LIEUTENANT GOVERNOR

LEO G. CASIL
DEPUTY DIRECTOR

Honorable Michael F.Q. San Nicolas Chair, Committee on Aviation, Ground Transportation, Regulatory Concerns and Future Generations 155 Hesler St. Hagatna, GU 96910

RE: Letter in Support of Bill No. 264-32(COR), AN ACT RELATIVE TO PROHIBITING THE SALE OR DISTRIBUTION OF ELECTRONIC CIGARETTES TO MINORS, BY ADDING A NEW § 6400 OF ARTICLE 4, CHAPTER 6, TITLE 11 GUAM CODE ANNOTATED.

Dear Senator San Nicolas,

My name is James Gillan and I am the Director of the Department of Public health and Social Services.

Thank you for the opportunity to provide testimony on Bill 264-32(COR), relative to the Prohibition and Sale or Distribution of Electronic Cigarettes to Minors.

As you know, Electronic Cigarettes or e-Cigarettes are a vapor based delivery system for nicotine, inhaled directly into the lungs. Nicotine is a highly addictive drug and may cause health and safety concerns when inhaled, ingested or comes in direct contact with skin. It can also cause nicotine poisoning in small children when ingested.<sup>1</sup>

Currently e-Cigarettes are not regulated by U.S. Food and Drug Administration (FDA), so there is no requirement to report on the actual contents of each cartridge. Cartridges contain a mixture typically made up of nicotine, propylene glycol and other chemicals, as well as a choice of flavors that are attractive to youth, like "vivid vanilla," "cherry crush" and chocolate. However, initial lab tests conducted by FDA found detectable levels of carcinogens and toxic chemicals, including an ingredient used in anti-freeze in two brands of e-cigarettes and numerous cartridges. <sup>3</sup>

Nationally, e-Cigarette experimentation and recent use among Middle and High School youth has more than doubled, between 2011 and 2012. Approximately 1.8 million students have ever

World Health Organization. Questions and answers on electronic cigarettes or electronic nicotine delivery systems (ENDS). Statement by WHO. July 9, 2013. Available online at <a href="http://www.who.int/tobacco/communications/statements/eletronic\_cigarettes/en/">http://www.who.int/tobacco/communications/statements/eletronic\_cigarettes/en/</a>

<sup>&</sup>lt;sup>2</sup> Campaign for Tobacco Free Kids. CDC Survey Finds Youth E-Cigarette Use More than Doubled from 2011-2012, Shows Urgent Need for FDA Regulation. Statement by Matthew L. Myers, President, Campaign for Tobacco-Free Kids. September 5, 2013. Available online at <a href="http://www.tobaccofreekids.org/press\_releases/post/2013\_09\_05\_ecigarettes/?utm\_source=home&utm\_inedium=carousel&utm\_campaign=home">http://www.tobaccofreekids.org/press\_releases/post/2013\_09\_05\_ecigarettes/?utm\_source=home&utm\_inedium=carousel&utm\_campaign=home</a>
<sup>3</sup> U.S. Food and Drug Administration. Summary of Results: Laboratory Analysis of Electronic Cigarettes Conducted by FDA. July 22, 2009. Available online at <a href="http://www.fda.gov/NewsEvents/PublichealthFocus/ucm173146.htm">http://www.fda.gov/NewsEvents/PublichealthFocus/ucm173146.htm</a>

Director James Gillan, Testimony on Bill 264-32(COR) January 21, 2014 Page 2 of 2

used an e-Cigarette, and just over 80% of those high school students also reported current conventional cigarette smoking.<sup>4</sup>

E-Cigarette advertising mimics the look and the behaviors of smoking a traditional cigarette. The two BIG Tobacco companies are joining in, Altria Group Inc., makers of Marlboro cigarettes and Reynolds American Inc., makers of Camel,<sup>5</sup> and are easily spending millions of dollars in their marketing campaign to re-glamorize 'smoking' by using celebrities, sexual innuendo and play on words, to promote their products and entice youth to try their product and become addicted. New ads are out on television, giving the industry a wider audience. Not since 1971 have there been any advertisements allowed on television for cigarettes. E-Cigarette sales in 2013 were expected to be over \$1 billion dollars. That amount is expected to jump over \$3 billion by 2015.<sup>6</sup> This smacks of history repeating itself with cigarette and other tobacco product advertising, and a new generation of addicted e-Cigarette users.

E-Cigarettes are not regulated and actual content in the cartridges are unknown which poses health and safety concerns, especially in the wellbeing and normal growth of our youth. In addition, Nicotine is a highly additive drug and the probability that continued use of e-Cigarettes will lead to use of traditional cigarettes and other tobacco products is great. Additional efforts to be considered in reducing youth access would be to require the e-Cigarettes and it's paraphernalia to be kept behind counters like other tobacco products, as well as requiring clearly marked signage that includes No E-Cigarette Sales to Minors. We must do what we can to protect our children from those unforeseen hazards.

Forty State Attorneys General and all State and Territorial Health Officials have requested the Food and Drug Administration to prioritize the regulation of this product. Indeed, we perhaps not just limit the sale of these Nicotine Delivery Systems to persons under 18 years of age, should consider very seriously tax the devices and the nicotine solutions as we do every tobacco product.

The DPHSS supports the intent of Bill 264-32(COR) to prohibit the sale or distribution of electronic cigarettes to minors and will to work in partnership to aid in policies that aim to reduce tobacco use and increase a healthier population and environment.

Sincerely,

James W. Gillan

7-12.2014

<sup>&</sup>lt;sup>4</sup> Centers for Disease Control and Prevention. Electronic Cigarette Use Among Middle and High School Students – United States, 2011-2012. Morbidity and Mortality Weekly Report. September 6, 2013 / Vol. 62 / No. 35. Available online at: <a href="http://www.cdc.gov/mmwr/pdf/wk/mm6235.pdf">http://www.cdc.gov/mmwr/pdf/wk/mm6235.pdf</a>

<sup>&</sup>lt;sup>5</sup> The Wall Street Journal, Holy Smokes: E-Cigarette Ads Debut on TV. Mike Estrel, December 26, 2013. Available online at: http://online.wsj.com/news/articles/SB10001424052702304753504579282752217648562

<sup>&</sup>lt;sup>6</sup> Forbes. E-cigarette Sales Surpass \$1 Billion as Big Tobacco Moves In. Natalie Robehmed. September 17, 2013. Available online at: http://www.forbes.com/sites/natalierobehmed/2013/09/17/e-cigarette-sales-surpass-1-billion-as-big-tobacco-moves-in/2/



## **E-Cigarettes**

#### Are they safe? Will they help smokers quit?

Electronic cigarettes or "e-cigarettes" are battery-operated devices that allow the user to inhale a vapor produced from cartridges filled with nicotine, flavor and other chemicals. E-cigarette companies promote them as healthier, convenient, and more socially acceptable alternatives to traditional cigarettes.

There is <u>no</u> scientific evidence that e-cigarettes are safe or that they can help smokers quit.

#### What are E-Cigarettes?

- According to the U.S. Food and Drug Administration (FDA), e-cigarettes are combination drug-device products designed to deliver nicotine or other substances to a user in the form of a vapor.<sup>1</sup> FDA does not consider e-cigarettes to be tobacco products.
- Despite FDA's view on these products, a federal appeals court has ruled that e-cigarettes are tobacco products rather than drug-devices. Unless manufacturers make therapeutic claims, e-cigarettes may only be regulated as tobacco products under the court's current decision. While the court denied a subsequent request for appeal from FDA and public health advocates, the case may still be appealed to the U.S. Supreme Court.
- E-cigarettes are not traditional cigarettes. They are typically composed of a rechargeable, battery-operated heating element, a replaceable cartridge that may contain nicotine or other chemicals, and an atomizer that uses heat to convert the contents of the cartridge into a vapor, which is then inhaled by the user.<sup>2</sup>
- Some e-cigarettes contain nicotine, a highly addictive drug<sup>3</sup>.

#### Safety and Cessation Concerns

- There is currently no scientific evidence about the safety of e-cigarettes. In initial lab tests, FDA found detectable levels of carcinogens (nitrosamines) and toxic chemicals, including an ingredient used in anti-freeze, in two brands of e-cigarettes and numerous cartridges. FDA determined that users could potentially be exposed to these chemicals.<sup>4</sup> This contradicts manufacturers' claims<sup>5,6,7</sup> that their products are safe alternatives to tobacco.
- E-cigarettes have not been approved by the FDA for use in smoking cessation. No evidence exists to show they help people quit smoking.<sup>8</sup>
- More research on e-cigarettes is needed to determine what ingredients they contain, how they are being used, and what effect they have on users.

#### Marketing and Youth Access Concerns

- Despite the fact that e-cigarettes have not been shown to be effective tobacco cessation tools, some distributors are marketing them either directly or indirectly for that purpose.
- In one study, FDA found that some e-cigarette cartridges claiming not to contain nicotine actually did. 10
- Government agencies and medical organizations, such as the FDA, the Centers for Disease Control and Prevention, and the American Academy of Pediatrics have also expressed concern that e-cigarettes could increase nicotine addiction and tobacco use in youth.
- E-cigarettes are often made to resemble traditional cigarettes and can be available in flavors appealing to youth. E-cigarettes may also lead youth to try traditional cigarettes or other tobacco products, which are known to cause disease and premature death.<sup>13</sup>
- Many nicotine refill bottles or cartridges are not adequately packaged to prevent children's
  access or accidental ingestion of toxic amounts of nicotine.

## Recent Court Ruling on E-Cigarettes

In December 2010, the DC Circuit Court of Appeals struck down FDA's authority to regulate e-cigarettes as drug-delivery devices unless manufacturers make health or cessation claims for their products. FDA wanted to use more stringent "drug" and "device" regulations to determine whether the products should even be permitted on the market. Unfortunately, the court held that ecigarettes would more appropriately be classified as "tobacco products," now that FDA has the authority to regulate tobacco products under the Family Smoking Prevention and Tobacco Control Act (FSPTCA). This decision means that with respect to e-cigarettes, as with tobacco products, no state or locality can require something different or in addition to the FDA's tobacco product standards, pre-market review, adulteration, misbranding, labeling, registration, good manufacturing standards, or modified risk claims. However, states and localities CAN enact. laws/standards that are more stringent with respect to prohibition of sales, distribution, exposure to, access to, advertising or promotion of, or use of tobacco products.

#### ACS CAN's Current Views

- ACS CAN believes that because nicotine is a drug, e-cigarettes are drug-delivery devices, rather than tobacco products, and should be regulated under FDA's drug and device authority and not available for sale until FDA determines they are safe.
- The DC Circuit Court's December 2010 ruling (explained at left) is problematic because the laws governing tobacco products allow them to be on the market under different product and marketing standards than the safety and efficacy standards applicable to drugs and medical devices. Allowing the FDA to regulate e-cigarettes as drug-delivery devices would give them the authority to study the products, as well as take greater action to protect and advance the public health.
- ACS CAN supports including e-cigarettes in new smoke-free laws or amendments to existing laws. However, due to the legal action surrounding the regulation of e-cigarettes, they should clearly be defined as different from tobacco products and addressed separately in the law.
- Regardless of the marketing tactics that ecigarette companies use, ACS CAN supports restricting the sale of e-cigarettes until evidence shows that these products are not harmful.
- Laws that only prohibit sales to minors do not go far enough to protect public health.

#### References

<sup>&</sup>lt;sup>1</sup> U.S. Food and Drug Administration. FDA and Public Health Experts Warn About Electronic Cigarettes. July 22, 2009. Available online at http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm173222.htm.

<sup>&</sup>lt;sup>2</sup> U.S. Food and Drug Administration. E-Cigarettes: Questions and Answers. September 17, 2010. Available online at <a href="http://www.fda.gov/ForConsumers/ConsumerUpdates/ucm225210.htm">http://www.fda.gov/ForConsumers/ConsumerUpdates/ucm225210.htm</a>.

<sup>&</sup>lt;sup>3</sup> National Institute on Drug Abuse. Tobacco/Nicotine, Available at http://www.nida.nih.gov/drugpages/nicotine.html.

<sup>&</sup>lt;sup>4</sup> U.S. Food and Drug Administration. Summary of Results: Laboratory Analysis of Electronic Cigarettes Conducted by FDA. July 22, 2009. Available online at <a href="http://www.ida.gov/NewsEvents/PublicHealthFocus.ucm173140.htm">http://www.ida.gov/NewsEvents/PublicHealthFocus.ucm173140.htm</a>.

<sup>&</sup>lt;sup>5</sup> The E-Cigarettes Shop. Electronic Cigarettes - A Healthier Alternative to Smoking. Available online at <a href="http://theecigarettes.com/electronic-cigarettes-a-healthier-alternative-to-smoking/">http://theecigarettes.com/electronic-cigarettes-a-healthier-alternative-to-smoking/</a>.

<sup>&</sup>lt;sup>6</sup> ECigarettesUSA, Inc. ECigarettes...a healthier alternative to cigarettes. Available at http://www.ecigarettesusa.com/.

<sup>&</sup>lt;sup>7</sup> The Safe Cig. Electronic Cigarette FAQs. Available online at <a href="http://www.thesafecig.com/contactus.php">http://www.thesafecig.com/contactus.php</a>.

<sup>&</sup>lt;sup>8</sup> World Health Organization. Marketers of Electronic Cigarettes Should Halt Unproven Therapy Claims. September 19, 2008. Available online at <a href="http://www.who.int/mediacentre/news/releases/2008/pr.34/en/">http://www.who.int/mediacentre/news/releases/2008/pr.34/en/</a>.

<sup>&</sup>lt;sup>9</sup> U.S. Food and Drug Administration. FDA Acts Against 5 Electronic Cigarette Distributors. September 9, 2010. Available online at http://www.fda.gov/Newsfivents/Newsroom/Press/Announcements/ucm225224.htm.

<sup>&</sup>lt;sup>10</sup> U.S. Food and Drug Administration. Summary of Results: Laboratory Analysis of Electronic Cigarettes Conducted by FDA. July 22, 2009. Available online at <a href="http://www.fdi.gov/NewsEvents/PublicHealthFocus/ucm173146.htm">http://www.fdi.gov/NewsEvents/PublicHealthFocus/ucm173146.htm</a>.

<sup>11</sup> U.S. Food and Drug Administration. FDA and Public Health Experts Warn About Electronic Cigarettes.

<sup>&</sup>lt;sup>12</sup> U.S. Food and Drug Administration. FDA Warns of Health Risks Posed by E-Cigarettes. July 23, 2009, Available online at <a href="http://www.lda.gov/ForConsumers/Consumert.pdates/uem173401.htm">http://www.lda.gov/ForConsumers/Consumert.pdates/uem173401.htm</a>.

Honorable Senator Dennis G. Rodrigues, Jr.

32<sup>nd</sup> Guam Legislature 176 Serenu Avenue Suite 107 Tamuning, Guam 96913

Hafa Adai!

I sit before you on behalf of the Non-Communicable Disease Consortium Tobacco Control Team in giving our full support of Bill 264-32 (An Act Relative to Prohibiting the Sale or Distribution of Electronic Cigarettes to Minors, by Adding a New § 6101(1), to Article 1, and Amending § 6400 of Article 4, Chapter 6, Title 11, Guam Code Annotated).

Originally known as Electronic Nicotine Delivery System (ENDS), it was patented in 1963 but resurfaced as Electronic Cigarettes in 2003; its popularity in the last 10 years has brought sales to over \$1 billion dollars in the United States. It is expected that sales will eclipse over \$3 billion dollar, next year, just in the United States alone.

Locally, the surge of its popularity has seen several businesses rooting up to fulfill this demand. The recent demand for Electronic Cigarettes has also accompanied misguided information that in reality has the possibility of adverse health consequences to our island

I would like to concentrate on two important facts pertaining to Electronic Cigarettes.

First is the main ingredient of the Electronic Cigarettes: nicotine.

The Diagnostic & Statistical Manual (DSM-IV) which is typically considered the "Bible" for Psychiatric/Substance-Related diagnoses clearly cites Nicotine Use Disorder and Nicotine-Induced Disorder.

Nicotine Use Disorder specifically keys on Nicotine Dependence (305.1) and its criteria with or without Physiological Dependence. The tolerance developed over a period of time creates the level of dependence the user experiences during any time frame of absences. Currently, the uncertainty of long term use of nicotine just has not been established.

Nicotine—Induced Disorder examines Nicotine Withdrawal (292.0) and the characteristic syndrome/symptoms that develops because of its use. Dysphoric or depressed mood/ insomnia/ irritability, frustration, or anger/ anxiety/ difficulty concentrating/ restlessness/ decreased heart rate/ increased appetite or weight gain are the major symptoms one can experience.

Clearly, the Electronic Cigarettes simply put is just another form of delivery to maintain nicotine into the human body. Because of the path electronic cigarettes has created the second important fact I would like to touch on is the concern of underage use.

Currently, CDC has estimated 25% of high school students have used electronic cigarettes.

Big tobacco companies have found yet another method of delivery specifically aimed at the younger generation of society. The absence of any regulatory monitoring has put this population at dire risk. Its accessibility, simplicity of operation and endless amount of flavors or commonly known as e-juicing has made this product so popular with the youth.

Locally, public school bus drivers have witness a surge in the use of e-cigarettes both at bus stop locations as well as on-board during transport. Use of e-cigarettes at various schools of GDOE has administration concerned. GDOE is currently taking action to control this epidemic.

The absences of any regulation of the production of electronic cigarettes also questions it use as a replacement therapy. The inconstancy of the nicotine liquid puts any user in danger especially used as a Nicotine Replacement Therapy (NRT). Currently, this device has not been approved as a cessation tool for assisting individuals wanting to live a tobacco-free lifestyle.

Simply put, we currently do not know the long term ramification Electronic Cigarettes or Nicotine has on the human body.

The two reasons that I have stated, should clearly send a message that Nicotine can be as deadly as any form of tobacco product that are currently on the market.

For this reason, on behalf of the Tobacco Control Group of the Non-Communicable Disease Consortium we strongly urge you to pass Bill 264-32 for a healthier smoke free/vap free Guam.

Sincerely,

Peter J. Cruz.

Co/Leader, Tobacco Control Group

Non-Communicable Disease Consortium



American Cancer Society Cancer Action Network 2370 Nu'uanu Avenue Honolulu, Hawai'i 96817 808.432.9149 www.acscan.org

32<sup>nd</sup> Legislature of Guam
Committee on Aviation, Ground
Transportation, Regulatory Concerns, and Future Generations
Senator Michael F.Q. San Nicolas, Chair
Senator Thomas C. Ada, Vice Chair
Speaker Judith T. Won Pat, Ed.D., Member
Vice-Speaker Benjamin J.F. Cruz, Member
Senator Aline A. Yamashita, Ph.D., Member
Senator Vicente C. Pangelinan, Member
Senator Rory J. Respicio, Member
Senator V. Anthony Ada, Member
Senator Tina Rose Muña Barnes, Member

Bill 264-32: An act to relative to prohibiting the sale or distribution of electronic cigarettes to minors, by adding a new § 6101(I) to Article 1, and amending § 6400 of Article 4, Chapter 6, Title 11 Guam Code Annotated.

Cory Chun, Government Relations – Hawaii Pacific Region American Cancer Society Cancer Action Network

Thank you for the opportunity to provide written comments in support of Bill 264-32, which prohibits the sale of electronic cigarettes to minors.

The American Cancer Society Cancer Action Network (ACS CAN) is the nation's leading cancer advocacy organization. ACS CAN works with federal, state, and local government bodies to support evidence-based policy and legislative solutions designed to eliminate cancer as a major health problem.

According to the U.S. Food and Drug Administration (FDA), e-cigarettes are combination drug-device products designed to deliver nicotine or other substances to a user in the form of a vapor. They are not traditional cigarettes. They are typically composed of a rechargeable, battery-operated heating element, a replaceable cartridge that may contain nicotine or other chemicals, and an atomizer that uses heat to convert the contents of the cartridge into a vapor, which is then inhaled by the user. Some e-cigarettes contain nicotine, a highly addictive drug.

E-cigarettes are often made to resemble cigarettes and available in flavors that may appeal to youth. E-cigarettes may also lead youth to try traditional cigarettes or other tobacco products, which are known to cause disease and premature death.

We would recommend a definition of electronic cigarette to include all types of electronic devices, delivering nicotine or other chemicals, included in the following definition:

"Electronic smoking device" means any electronic product that can be used to simulate smoking in the delivery of nicotine or other substances to the person inhaling from the device, including but not limited to an electronic cigarette, electronic cigar, electronic cigarillo, or electronic pipe, and any cartridge or other component of the device or related product.

The use of e-cigarettes has the potential to result in smoking again becoming a socially acceptable behavior, undoing decades of work that has made smoking socially unacceptable and substantially decreasing the death and disease from traditional cigarette use. Prohibiting the sale of these devices, regardless of nicotine content, would prevent youth from normalizing the use of these products and becoming accustomed to the act of smoking.

Thank you for the opportunity to provide written comments on this important issue.

# Testimony on Legislative Bill #264–32: Prohibiting Sale of e-cigarettes to Minors

#### By Ken Leon-Guerrero

I agree with this bill, in principle, but I think it doesn't go far enough to protect the children and people of Guam. I am here to testify today about the urgency we have here on Guam to pass a bill that recognizes e-cigarettes for what they really are cigarettes.

This is a good first step and I appreciate that the legislation as written recognizes the risks these devises pose to the youth of Guam. Every morning I walk my dogs through the Village of Santa Rita, and along the way I pass numerous school bus stops. Over the past year I have noticed an increasing number of pre—teens and teenagers smoking e-cigarettes at the bus stops. On March 6<sup>th</sup> of this year, a study released by the University of California at San Francisco (Attachment 1) reported that a study of 40,000 middle and high schools students on smoking behaviors found e-cigarettes are leading to a dramatic increase in smoking by pre-teens and teenagers. The same study cited and I quote:" They are sold in flavors such as chocolate and strawberry that are banned in conventional cigarettes because of their appeal to youth."

The fact that e-cigarettes are offering a selection of "Youth Favored" flavors becomes important when you consider the fact that another recent study released on Youth Smoking Habits by the CDC in November of 2013 (Attachment 2) revealed that 90% of all adult smokers were smoking by the time they were 18.

I remember back when I was a kid and the stores sold cigarette bubble gum. I remember how all the kids would blow the powder out of them pretending they were smoking, and most of them went on to become smokers. I am concerned that growing use of e-cigarettes by adults as a way of circumventing existing laws on cigarette smoking in public places and the ease of purchase of the devices by minors combined with the availability of "flavored nicotine formulas," will create a simple pathway to a lifelong addiction and health problems for new generations of child nicotine addicts.

The authors of the UCSF study supports my concerns when they documented troubling trends heir report:

"The (report) authors found that the devices were associated with higher odds of progression from experimenting with cigarettes to becoming established cigarette

smokers. Additionally, adolescents who smoked both conventional cigarettes and e-cigarettes smoked more cigarettes per day than non-e-cigarette users."

But this bill as written does not go far enough. Every day I see evidence that backs up the research findings claim that smokers who use e-cigarettes smoke more than they did before they began using e-cigarettes. Most of the people I know who still smoke cigarettes; smoke more than they did before they began using e-cigarettes. They are smoking in their offices and they are smoking in public places. Smokers I know who would never smoke in the house, or in a car with passengers now smoke in their homes and in their cars with passengers. Worse than that, they think nothing of smoking them around small children.

When we look at the history of cigarette evolution, there has been a consistent effort by cigarette manufacturers to build market share and profits by making tobacco more addicting. I have yet to see or read any study that says conclusively that the e-cigarettes are safer than regular cigarettes. In fact the fact the delivery systems of e-cigarettes all chemical based leads me to believe the opposite. How can anyone claim they are safer for children or adults when e-cigarettes contain nicotine like conventional cigarettes?

In preparing for my testimony today, I read an FDA analysis of the chemicals used in e-cigarettes and was surprised to learn that among long list of toxic chemicals used in e-cigarette solutions, the FDA detected diethylene glycol which is a toxic compound found in antifreeze.

In 2006, in Panama more than 700 people were poisoned ingesting cold medicine tainted with diethylene glycol; and of that number 123 people died, before the product was pulled from the shelves. Since when do we think having children or even adults inhale antifreeze is a good idea?

Let's look at a few of the other chemicals found in the e-cigarette solution by the FDA:

**Acetaldehyde** is a harmful compound as it reacts with other compounds within the body common to everyday life. When acetaldehyde cannot be converted into acetic acid in the body, problems can arise. Acetaldehyde is absorbed through respiratory and oral passages and then distributed throughout the body through different metabolic tracts. The most common tracts in which this occurs are in the respiratory and liver tracts.

**Benzene** irritates the linings of the airways. Exposure to low concentration benzene vapors can cause inflammation of the nasal airways and throat. High-level exposure can severely damage the lungs causing fluid accumulation and bleeding, which is often fatal. When abused in large doses through huffing, benzene is rapidly absorbed into the blood stream and travels to the brain with devastating effects. Stupor, delirium, and drowsiness give way to seizures and coma. Fluid

accumulates in the lungs compromising breathing; there is poor oxygen absorption from the air. Intensive treatment is necessary to prevent death.

**Cadmium** is one of the most toxic elements to which man can be exposed at work or in the environment. Once absorbed, Cadmium is efficiently retained in the human body, in which it accumulates throughout life. Cadmium is primarily toxic to the kidney, especially to the proximal tubular cells, the main site of accumulation. Cadmium can also cause bone demineralization, either through direct bone damage or indirectly as a result of renal dysfunction. In the industry, excessive exposures to airborne Cadmium may impair lung function and increase the risk of lung cancer.

**Formaldehyde** exposure can cause irritation and burning of the mucous membranes of the nose, mouth and upper respiratory tract. Some adverse effects following acute exposure to large amounts of formaldehyde may include weakness, headache, nausea, vomiting, pneumonia, dyspnoea, wheezing, coughing, laryngeal and pulmonary oedema, bronchospasm, laryngeal spasm, respiratory depression, obstructive tracheo-bronchitis, central nervous system depression, convulsions and coma.

**Lead** poisoning is a very serious matter. When gets inside the body, the body confuses it with calcium and other essential nutrients. This confusion can cause permanent damage to the health of both children and adults. Lead is a "developmental toxicant" and the harmful effects of lead on children's development can occur without signs or symptoms according to the CDC.

Even at **low levels**, lead can be harmful and be associated with:

- Learning disabilities resulting in a decreased intelligence (decreased IQ)
- Attention deficit disorder
- Behavior issues
- Nervous system damage
- Speech and language impairment
- Decreased muscle growth
- Decreased bone growth
- Kidney damage

**Nickel** expose is currently under study, but so far reporst has shown that the there have been respiratory effects reported in humans from inhalation exposure to nickel. Human and animal studies have reported an increased risk of lung and nasal cancers from exposure to nickel

refinery dusts and nickel subsulfide. Animal studies of soluble nickel compounds (i.e., nickel carbonyl) have reported lung tumors.

**Nicotine** is an active chemical substance present in tobacco that contributes to the negative reputation of tobacco. This chemical, when abused (through smoking or chewing) has harmful effects on the human body and it is also found to be as addictive as illegal drugs. The below are a few harmful and addictive effects of nicotine on humans, later followed by long and short-term effects.

Harmful effects: Nicotine harms every organ of the body. It affects lungs, heart, kidneys, digestive system, liver, eyes and many other vital organs in the body. Further, people who smoke tobacco get their sense of smell and taste weakened. Also 'passive smoking' or 'secondhand smoking' harms non-smokers. The tobacco smoke contains harmful chemicals. When inhaled by non-smokers in the smoker's proximity, it causes coughing, phlegm and decline in the functionality of the lungs. Studies show that it can cause heart diseases even among non-smokers who are subjected to secondhand smoking.

Addictive effects: Nicotine is absorbed into the body when an individual smokes or chews tobacco. Nicotine causes elevation of mood. This is the principal reason for nicotine causing addiction. The nicotine absorbed by a smoker reaches the brain via blood. This leads to numerous chemical reactions in the brain and causes feeling of high. It lasts for a short span. Once the nicotine level declines, there is no longer the high-feeling. To have a similar feeling again, the smoker has to smoke again, thus it causes addiction.

<u>Short-term effects of nicotine</u>: In the short-term, nicotine is found to cause high blood pressure, increased pulse rate and cough. The abuse of nicotine also has immediate effects on oral cavity which causes bad breath and staining of teeth. In severe cases, it may also lead to oral cancer.

<u>Long-term effects of nicotine</u>: Long-term effects of nicotine include addiction, increased risk of heart diseases, and decline in insulin levels, cancer and premature aging. Long-term effects of nicotine are very harmful and may also lead to fatalities in many cases.

**N-Nitrosonornicotine** a nitrosamine compound that is toxic if ingested and may be harmful if inhaled or absorbed through the skin. It may cause irritation to the gastrointestinal tract, respiratory tract, skin, and eyes. It is classified by IARC as Group 2B, possibly carcinogenic to humans. *N*-Nitrosonornicotine is used as a research chemical. It is found in a variety of tobacco

products. *N*-Nitrosonomicotine is toxic if ingested and may be harmful if inhaled or absorbed through the skin. It may cause irritation to the respiratory tract, gastrointestinal tract, skin, and eyes. It is classified by IARC as Group 2B, possibly carcinogenic to humans. It may cause adverse effects to the liver. Prolonged exposure may result in serious illness or death.

**Toluene** is an aromatic hydrocarbon, occurring naturally in crude oil and in the tolu tree. Once inhaled, the extensive capillary surface of the lungs allows rapid absorption of toluene and blood levels peak rapidly. Entry into the brain is extremely fast and onset of effects is almost immediate. Toluene effects generally last several hours.

Toluene can cause brain, liver and kidney damage, hearing loss, memory impairment, and attention deficits. Death can result from heart failure, asphyxiation or aspiration. Toluene also owes its pharmacology to a mucosal irritant effect from an exothermic reaction with water. This results in vomiting, lacrimation and ocular burning, cough, chest pain, wheezing and possible interstitial edema, and kidney toxicity with tubular acidosis. Toluene exposure is also associated with a transient liver injury.

Toluene is produced during the process of making gasoline and other fuels from crude oil, in making coke from coal, and as a by-product in the manufacture of styrene. Toluene has numerous commercial and industrial applications and is a solvent in paints, lacquers, thinners, glues, correction fluid and nail polish remover, and is used in the printing and leather tanning processes.

Due to its easy accessibility, low cost and ease of concealment, some U.S. states have placed restrictions on the sale of these products to minors. It is frequently abused for its intoxicating effects. Recreational use is most common among younger adolescents primarily because it is readily available, inexpensive and legal.

According to a report issued by the Cancer Prevention and Treatment Fund (Attachment 3):

"The percentage of teenagers who have tried e-cigarettes has more than doubled in just a year, from 4.7% in 2011 to 10% in 2012. Over 1.78 million U.S. students in middle school and high school tried e-cigarettes in 2012, according to the National Youth Tobacco Survey. Furthermore, 1 in 5 middle schoolers who said they had tried e-cigarettes also said they had never smoked conventional cigarettes.

This is worrisome for two reasons:

- 1) the younger people are when they begin smoking, the more likely it is they will develop the habit: nearly 9 out of 10 smokers start before they are 18.
- 2) e-cigarettes will introduce many more young people to smoking who might otherwise never have tried it, and once they are addicted to nicotine, some may decide to get their "fix" from regular cigarettes.

Whether e-cigarettes end up being a "gateway" to regular cigarettes or not, young people who use them risk becoming addicted to nicotine and exposing their lungs to harmful chemicals."

We are twenty to thirty years away from learning the "TRUE COST" and impact that ecigarettes and their toxic chemical cocktail are going to have on people from direct use and secondhand exposure. Let's not sacrifice another generation to the ravages of chemical experimentation in pursuit of corporate profit.

The only positive thing that has been touted in all the reports and studies on e-cigarettes that I have been able to read (and I have read a lot of them preparing for this testimony) is summed up best in the quote below from a review on e-cigarettes issued by the CDC:

"Despite positive reviews from e-cigarette users who enjoy being able to smoke them where regular cigarettes are prohibited, very little is known about their safety and long-term health effects."

When you take that finding into consideration in addition to local observations; the same circumstances are happening and growing here on Guam.

We need to follow the example of the California state senate (SB 648) which in May 2013, proposed a law making e-cigarettes subject to all of the same regulations and restrictions as traditional cigarettes and tobacco products.

I think to protect our children and the rest of the people of Guam, we need to take the same approach and call e-cigarettes what they are...cigarettes; and regulate their use in the same manner as regular cigarettes.

# Attachment 1

# E-Cigarettes: Gateway to Nicotine Addiction for U.S. Teens, Says UCSF Study

# First National Analysis Strongly Associates E-Cigarettes with Smoking for Many Adolescents

By Elizabeth Fernandez on March 06, 2014

E-cigarettes, promoted as a way to quit regular cigarettes, may actually be a new route to conventional smoking and nicotine addiction for teenagers, according to a new UC San Francisco study.

In the first analysis of the relationship between e-cigarette use and smoking among adolescents in the United States, UCSF researchers found that adolescents who used the devices were more likely to smoke cigarettes and less likely to quit smoking. The study of nearly 40,000 youth around the country also

found that e-cigarette use among middle and high school students doubled between 2011 and 2012, from 3.1 percent to 6.5 percent.

"Despite claims that e-cigarettes are helping people quit smoking, we found that e-cigarettes were associated with more, not less, cigarette smoking among adolescents," said lead author <u>Lauren Dutra</u>, a postdoctoral fellow at the <u>UCSF Center for Tobacco</u> Control Research and Education.

"E-cigarettes are likely to be gateway devices for nicotine addiction among youth, opening up a whole new market for tobacco," she said.

The study was published online on March 6 in JAMA Pediatrics.



E-cigarettes are battery-powered devices that look like cigarettes and deliver an aerosol of nicotine and other chemicals. Promoted as safer alternatives to cigarettes and smoking cessation aids, the devices are rapidly gaining popularity among adults and youth in the U.S. and around the world. Unregulated by the U.S. Food and Drug Administration, e-cigarettes have been widely promoted by their manufacturers as a way for people to quit smoking conventional cigarettes. They are sold in flavors such as chocolate and strawberry that are banned in conventional cigarettes because of their appeal to youth.

In the new UCSF study, the researchers examined survey data from middle and high school students who completed the National Youth Tobacco Survey in 2011 and 2012.

The authors found that the devices were associated with higher odds of progression from experimenting with cigarettes to becoming established cigarette smokers. Additionally, adolescents who smoked both conventional cigarettes and e-cigarettes smoked more cigarettes per day than non-e-cigarette users.

Contrary to advertiser claims that e-cigarettes can help consumers stop smoking conventional cigarettes, teenagers who used e-cigarettes and conventional cigarettes were much less likely to have abstained from cigarettes in the past 30 days, 6 months, or year. At the same time, they were more likely to be planning to quit smoking in the next year than smokers who did not use e-cigarettes.

The study's cross-sectional nature didn't allow the researchers to identify whether most youths initiated with conventional cigarettes or e-cigarettes. But the authors noted that about 20 percent of middle school students and about 7 percent of high school students who had ever used e-cigarettes had never smoked regular cigarettes – meaning that some kids are introduced to the addictive drug nicotine through e-cigarettes, the authors said.

"It looks to me like the wild west marketing of e-cigarettes is not only encouraging youth to smoke them, but also it is promoting regular cigarette smoking among youth," said senior author <u>Stanton A. Glantz</u>, PhD, UCSF professor of medicine and director of the Center for Tobacco Control Research and Education.

The new results are consistent with a <u>similar study</u> of 75,000 Korean adolescents published last year by UCSF researchers, which also found that adolescents who used e-cigarettes were less likely to have stopped smoking conventional cigarettes.

In combination, the two studies suggest that "e-cigarettes may contribute to nicotine addiction and are unlikely to discourage conventional cigarette smoking among youths," said the scientists.

The federal Centers for Disease Control and Prevention reported last year that the majority of adolescents who have ever smoked e-cigarettes also have smoked regular cigarettes. An estimated 1.78 million U.S. students have used the devices as of 2012, the CDC reported.

The research was funded by the National Cancer Institute (grants CA-113710 and CA-060121).

The Center for Tobacco Control Research and Education specializes in tobacco control research focused on policy change, smoking cessation, nicotine addiction, health disparities in smoking, novel tobacco devices and tobacco marketing. It also houses the Legacy Tobacco Documents Library, a rich resource of previously confidential tobacco industry documents.

UCSF is a leading university dedicated to promoting health worldwide through advanced biomedical research, graduate-level education in the life sciences and health professions, and excellence in patient care. It includes top-ranked graduate schools of dentistry, medicine, nursing and pharmacy, a graduate division with nationally renowned programs in basic biomedical, translational and population sciences, as well as a preeminent biomedical research enterprise and two top-ranked hospitals, UCSF Medical Center and UCSF Benioff Children's Hospital.

# Attachment 2

### Centers for Disease Control and Prevention

CDC 24/7: Saving Lives. Protecting People.™

# Tobacco Product Use Among Middle and High School Students — United States, 2011 and 2012

Please note: An erratum has been published for this article. To view the erratum, please click here.

Weekly: November 15, 2013 / 62(45);893-897

Nearly 90% of adult smokers in the United States began smoking by age 18 years (*I*). To assess current tobacco product use among youths, CDC analyzed data from the 2012 National Youth Tobacco Survey (NYTS). This report describes the results of that analysis, which found that, in 2012, the prevalence of current tobacco product use among middle and high school students was 6.7% and 23.3%, respectively.

After cigarettes, cigars were the second most commonly used tobacco product, with prevalence of use at 2.8% and 12.6%, respectively. From 2011 to 2012, electronic cigarette use increased significantly among middle school (0.6% to 1.1%) and high school (1.5% to 2.8%) students, and hookah use increased among high school students (4.1% to 5.4%).

During the same period, significant decreases occurred in bidi\* and kretek† use among middle and high school students, and in dissolvable tobacco use among high school students. A substantial proportion of youth tobacco use occurs with products other than cigarettes, so monitoring and prevention of youth tobacco use needs to incorporate other products, including new and emerging products. Implementing evidence-based interventions can prevent and reduce tobacco use among youths as part of comprehensive tobacco control programs.

In addition, implementation of the 2009 Family Smoking Prevention and Tobacco Control Act, which granted the Food and Drug Administration (FDA) the authority to regulate the manufacture, distribution, and marketing of tobacco products  $(I-\underline{3})$ , also is critical to addressing this health risk behavior.

NYTS is a school-based, self-administered, pencil-and-paper questionnaire administered to U.S. middle school (grades 6–8) and high school (grades 9–12) students to collect information on key tobacco control outcome indicators used to monitor the impact of comprehensive tobacco control policies and programs (4) and FDA's newly granted regulatory authority. NYTS was conducted in 2000, 2002, 2004, 2006, 2009, 2011, and 2012. The 2012 NYTS used a three-stage cluster sampling procedure to generate a cross-sectional, nationally representative sample of students in grades 6–12. This report includes 2011 and 2012 NYTS data to provide an updated definition of current tobacco use, which now also includes hookahs, snus, dissolvable tobacco, and electronic cigarettes, to take into account nonconventional products that are new to the market or are increasing in popularity; data for these four products were first collected in 2011. The previous definition for current tobacco use did not include all of these products,

thus yielding slightly lower estimates of current tobacco use. For example, in 2011, the previous definition for overall current tobacco use resulted in estimates of 7.1% for middle school and 23.2% for high school students (5), whereas the new definition resulted in 2011 estimates of 7.5% for middle school and 24.3% for high school students (Table).

Of the 284 schools selected for the 2012 NYTS, 228 (80.3%) participated, resulting in a sample of 24,658 (91.7%) among 26,873 eligible students; the overall response rate was 73.6%. The 2011 NYTS had a comparable overall response rate of 72.7% ( $\underline{5}$ ). Respondents were asked about their current use of cigarettes, cigars§ (defined as cigars, cigarillos, or little cigars), smokeless tobacco, pipes, bidis, kreteks, hookahs, snus, dissolvable tobacco, and electronic cigarettes. For each product, current use was defined as using on  $\geq 1$  day of the past 30 days.

Data were adjusted for nonresponse and weighted to provide national prevalence estimates with 95% confidence intervals for current tobacco use overall and by product, school level, sex, and race/ethnicity. Point estimate differences between 2011 and 2012 were assessed using a two-tailed t-test for significance (p<0.05).

In 2012, 6.7% of middle students reported current use of any tobacco product (<u>Table</u>). The most commonly used forms of tobacco were cigarettes (3.5%), cigars (2.8%), pipes (1.8%), smokeless tobacco (1.7%), hookahs (1.3%), electronic cigarettes (1.1%), snus (0.8%), bidis (0.6%), kreteks (0.5%), and dissolvable tobacco (0.5%). Among high school students, 23.3% reported current use of any tobacco product. The most commonly used forms of tobacco were cigarettes (14.0%), cigars (12.6%), smokeless tobacco (6.4%), hookahs (5.4%), pipes (4.5%), electronic cigarettes (2.8%), snus (2.5%), kreteks (1.0%), bidis (0.9%), and dissolvable tobacco (0.8%).

During 2011–2012, among middle school students, for current electronic cigarette use, significant increases were observed overall (0.6% to 1.1%) and among females (0.4% to 0.8%), males (0.7% to 1.5%), and Hispanics (0.6% to 2.0%) (Table). For hookahs, a significant increase was observed among Hispanics (1.7% to 3.0%).

During 2011–2012, among high school students, for electronic cigarette use, significant increases were observed overall (1.5% to 2.8%) and among females (0.7% to 1.9%), males (2.3% to 3.7%), non-Hispanic whites (1.8% to 3.4%), and Hispanics (1.3% to 2.7%). For hookahs, significant increases were observed overall (4.1% to 5.4%) and among non-Hispanic whites (4.3% to 6.1%). For cigars, a significant increase in use was observed among non-Hispanic blacks (11.7% to 16.7%).

#### Reported by

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#### **Editorial Note**

The findings in this report indicate that during 2011–2012 significant increases occurred in current use of nonconventional tobacco products, such as electronic cigarettes and hookahs, among middle and high

school students; in addition, an increase in cigar use occurred among non-Hispanic black high school students. During this same period, overall current use of some tobacco products, such as bidis and kreteks, significantly decreased. These findings indicate that more efforts are needed to monitor and prevent the use of both conventional and nonconventional tobacco products among youths.

During 2011–2012, cigar use increased significantly among non-Hispanic black high school students to 16.7%, more than doubling the 2009 estimate (6). Further, cigar use among high school males (16.7%) was approximately double that of high school females (8.4%) and similar to cigarette use among high school males (16.3%). Cigars include traditional premium cigars as well as cigarillos and "little cigars," which are similar to cigarettes in terms of appearance, but depending on their weight, can be taxed at lower rates and legally sold with certain flavors that are banned from cigarettes (7).

Youths are known to have higher rates of cigar use than adults, which might be related to the lower price of some cigars (e.g., cigarillos and "little cigars") relative to cigarettes, or the marketing of flavored cigars that might appeal to youths (8).

Significant increases also were observed in overall use of current electronic cigarettes ( $\underline{9}$ ) and hookahs.

Current use of electronic cigarettes doubled among middle and high school females, middle school males, and Hispanic high school students. Among non-Hispanic white high school students, this increase was slightly less than double (1.8% to 3.4%), and among high school males, this increase was slightly more than 60% (2.3 to 3.7). For current hookah use, an increase of more than 75% (1.7% to 3.0%) was observed for Hispanic middle school students; among high school students, an overall increase of more than 30% (4.1% to 5.4%) was observed, but for non-Hispanic whites, this increase was more than 40% (4.3% to 6.1%).

The increase in use of electronic cigarettes and hookah tobacco could be attributed to low price, an increase in marketing, availability, and visibility of these products, and the perception that these tobacco products might be "safer" alternatives to cigarettes. Cigars, electronic cigarettes, hookah tobacco, and certain other new types of tobacco products are not currently subject to FDA regulation.

FDA has stated it intends to issue a proposed rule that would deem products meeting the statutory definition of a "tobacco product" to be subject to the Federal Food, Drug, and Cosmetic Act.¶

The findings in this report are subject to at least six limitations.

- First, data were only collected from youths who attended either public or private schools and might not be generalizable to all middle and high school-aged youths.
- Second, data were self-reported; thus, the findings are subject to recall and response bias.
- Third, current tobacco use was defined by including students who responded to questions about at least one of the 10 tobacco products but might have had missing responses to any of the other tobacco products that were assessed; missing responses were considered as nonuse, which might have resulted in conservative estimates.
- Fourth, in 2012, the question wording for bidis and kreteks was modified, and cigar brand
  examples were added to the heading and ever cigar use question of the survey; therefore, any

- observed changes in prevalence estimates across years might be attributed in part to these wording modifications.
- Fifth, the NYTS overall response rate of 73.6% in 2012 and 72.7% in 2011 might have resulted in nonresponse bias, even after adjustment for nonresponse.
- Finally, estimates might differ from those derived from other youth surveillance systems, in part because of differences in survey methodology, survey type and topic, and age and setting of the target population. However, overall relative trends are similar across the various youth surveys (1).

Effective, population-based interventions for preventing tobacco use among youths are outlined in the Surgeon General's report (I) and the World Health Organization's MPOWER package (I0). Interventions include increasing the price of all tobacco products, implementing 100% comprehensive smoke-free laws and policies in workplaces and public places, warning about the dangers of all tobacco use with tobacco use prevention media campaigns, increasing access to help quitting, and enforcing restrictions on all tobacco product advertising, promotion, and sponsorship.

Interventions are best implemented as part of comprehensive tobacco control programs, which are effective in decreasing tobacco use in the United States (2). Full implementation of comprehensive tobacco control programs at CDC-recommended funding levels, in coordination with FDA regulations of tobacco products, would be expected to result in further reductions in tobacco use and changes in social norms regarding the acceptability of tobacco use among U.S. youths (1,2,10).

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# Attachment 3

## Cancer Prevention & Treatment Fund

Information was can use. A voice you can trust.

Except from:

## **Are E-Cigarettes Safer Than Regular Cigarettes?**

BY SARAH MILLER, RN AND JESSICA BECKER/UPDATED SEPTEMBER 2013

The key difference between conventional and e-cigarettes is that e-cigarettes don't contain tobacco. But, it isn't just the tobacco in cigarettes that causes cancer. Conventional cigarettes contain a laundry list of chemicals that are proven toxic, and e-cigarettes have some of these same chemicals.

Nicotine is one of the chemicals found in both conventional and e-cigarettes. It is addictive and has been shown to reduce bone health.

An analysis of e-cigarettes by the FDA in 2009 found that they "contained detectable levels of known carcinogens and toxic chemicals to which users could be exposed". For example, in e-cigarette cartridges marketed as "tobacco-free," the FDA detected diethylene glycol (a toxic compound found in antifreeze), tobacco-specific nitrosamines which are carcinogenic to humans, and other toxic tobacco-specific impurities. The body's reaction to many of the toxic chemicals in conventional cigarette smoke causes chronic inflammation, which in turn leads to chronic diseases like bronchitis, emphysema, and heart disease. Since e-cigarettes also contain many of the same toxic chemicals, there is no reason to believe that they will lessen the risks for these diseases.

You may have also heard that free radicals produced by the smoke from cigarettes can damage veins and arteries and lead to heart disease. It is possible that the vapor from ecigarettes may contain fewer free radicals because it is not smoke. This does not mean, however, that smoking e-cigarettes is safe for your heart.

There are no long-term studies to back up claims that the vapor from e-cigarettes is less harmful than conventional smoke. Cancer takes years to develop, and e-cigarettes were only very recently introduced to the United States. It is almost impossible to determine if a product increases a person's risk of cancer or not until the product has been around for at least 15-20 years. Despite positive reviews from e-cigarette users who enjoy being able to smoke them where regular cigarettes are prohibited, very little is known about their safety and long-term health effects.

# CAN E-CIGARETTES BE USED TO CUT DOWN OR QUIT SMOKING REGULAR CIGARETTES?

If a company makes a claim that its product can be used to treat a disease or addiction, like nicotine addiction, it must present studies to the FDA showing that its product is safe and effective for that use. On the basis of those studies, the FDA approves or doesn't approve the product. So far, there are no good studies looking at whether e-cigarettes can be used to cut down or quit smoking long-term. The few short-term studies that have been done were with a small number of smokers who were not randomly selected.<sup>6</sup>

The FDA has not approved e-cigarettes for use in cessation, or quitting smoking.<sup>2</sup>

In September 2010, the FDA sent a <u>warning letter</u> to five distributors of e-cigarettes who were marketing their product this way: E-CigaretteDirect LLC, Ruyan America INC., Gamucci America (Smokey Bayou INC.), E-Cig Technology INC. and Johnson's Creek Enterprises LLC. After this warning letter, four of the companies changed their position to say that their e-cigarettes are *not* intended to be used as a way to quit smoking. E-Cig Technology INC. hasn't made any changes to their website in response to the warning letter.

While some people say that e-cigarettes are helping them smoke fewer regular cigarettes, those are just personal anecdotes, which is very different from science or evidence. It is likely that e-cigarettes will lead to more people smoking since the laws prohibiting smoking in many places do not apply to them.

#### **TEENAGERS AND E-CIGARETTES**

The percentage of teenagers who have tried e-cigarettes has more than doubled in just a year, from 4.7% in 2011 to 10% in 2012. Over 1.78 million U.S. students in middle school and high school tried e-cigarettes in 2012, according to the National Youth Tobacco Survey. Furthermore, 1 in 5 middle schoolers who said they had tried e-cigarettes also said they had never smoked conventional cigarettes. § This is worrisome for two reasons: 1) the younger people are when they begin smoking, the more likely it is they will develop the habit: nearly 9 out of 10 smokers start before they are 18; § 2) e-cigarettes will introduce many more young people to smoking who might otherwise never have tried it, and once they are addicted to nicotine, some may decide to get their "fix" from regular cigarettes. Whether e-cigarettes end up being a "gateway" to regular

cigarettes or not, young people who use them risk becoming addicted to nicotine and exposing their lungs to harmful chemicals.

The sharp rise in young e-cigarette users highlights the need to stop distributors from advertising e-cigarettes as a safe alternative to smoking tobacco.

#### HOW ARE E-CIGARETTES REGULATED?

Originally, the FDA tried to block the sale of e-cigarettes on grounds that they were an untested drug-delivery device (nicotine is a drug), but in 2010 a federal appeals court ruled that the FDA could only regulate e-cigarettes as tobacco products. <sup>10</sup> The FDA was given the authority to regulate the manufacturing, labeling, distribution and marketing of all tobacco products in 2009 when President Obama signed into law the <u>Family Smoking</u> Prevention and Tobacco Control Act.

Even with this new Act, the FDA's ability to regulate e-cigarettes is limited. However, individual states have the authority to implement more strict laws, or even ban e-cigarettes completely. For example, in May 2013, the California state senate proposed a law making all e-cigarettes subject to the same regulations and restrictions as traditional cigarettes and tobacco products. <sup>11</sup>

#### **BOTTOM LINE**

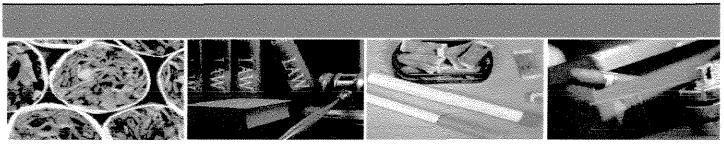
E-cigarettes have not been around long enough to determine if they are harmful to users in the long run. Studies by the FDA show that e-cigarettes contain some of the same toxic chemicals as regular cigarettes even though they don't have tobacco. Unfortunately, many people, including teenagers, are under the impression that e-cigarettes have been proven safe. Unless you want to be a guinea pig, hold off on e-cigarettes until more safety information is available. And if you want to quit smoking or reduce the number of cigarettes you are smoking, check out these <u>Quit Smoking Resources</u> compiled by the Centers for Disease Control (CDC).

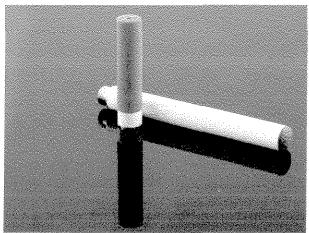
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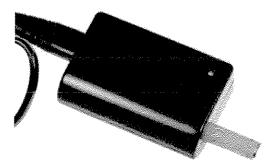
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# **Electronic Cigarettes**







An e-cigarette inserted into its charger. E-cigarettes are electronic devices used to deliver nicotine to the user in vapor form.

and Guam Law

## CHAPTER 40 GUAM FOOD, DRUG AND COSMETIC ACT

**NOTE:** P.L. 15-96 amended and renumbered Subchapter W of Chapter VI of Title X, which appears here as Chapter 40 of this Title.

- § 40101. Title.
- § 40102. Definitions.
- § 40103. Prohibited Acts.
- § 40104. Jurisdiction.
- § 40105. Penalty.
- § 40106. Tags for Adulterated Articles; Violations.
- § 40107. Institution of Proceedings.
- § 40108. Regulations under Federal Act Apply.
- § 40109. Adulterated Food.
- § 40110. Misbranded Food.
- § 40111. Imports.
- § 40112. Exemptions from Labeling Requirement.
- § 40113. Unsafe Substances.
- § 40114. Adulterated Drugs.
- § 40115. Misbranded Drugs.
- § 40116. Habit-Forming Drugs; Toxic Drugs.
- § 40117. Sale of New Drugs.
- § 40118. Adulterated Cosmetics.
- § 40119. Misbranded Cosmetics.
- § 40120. Labeling Requirements.
- § 40121, Advertising,
- § 40122. Regulations.
- § 40123. Inspections.
- § 40124. Report of Minor Violations.
- § 40125. Emergency Permit Control.
- § 40126. Reports of Judgment and Decrees.
- § 40127. Severability.
- § 40128, Effective Date.
- § 40129. Authorization.

#### § 40101. Title.

This Act may be cited as the "Guam Food, Drug and Cosmetic Act."

SOURCE: GC § 9720.

**NOTE:** The terms *this Act* and *Subchapter* were used synonymously in the original version of P.L. 13-143, with Subchapter being changed to Chapter here.

#### § 40102. Definitions.

For the purpose of this Act:

- (a) The *effective date* means the date this Act shall be implemented.
- (b) The *Director* means the Director of the Department of Public Health and Social Services.
- (c) The term *person* includes individual, partnership, corporation and association.
  - (d) The term *food* means:
    - (1) Articles used for food or drink for man or other animals;
    - (2) Chewing gum; and
    - (3) Articles used for components of any such article.
  - (e) The term drug means:
  - (1) Articles recognized in the official United States Pharmacopoeia, official Homeopathic Pharmacopoeia of the United States or official Nations Formulary, or any supplement to any of them; and
  - (2) Articles intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease in man or other animals; and
  - (3) Articles (other than food) intended to affect the structure of any function of the body of man or other animals; and
  - (4) Articles intended for use as a component of any article, specified in clause (1), (2) or (3); but does not include devices or their components, parts or accessories.
- (f) The term *counterfeit drug* means a drug which, or the container or labeling of which, without authorization, bears the trademark, trade name or other identifying mark, imprint or device, or any likeness thereof, of a drug manufacturer, processor, packer or distributor other than the person or persons who in fact manufactured, processed, packed or distributed such drug and which thereby falsely purports or is represented to be the product of, or to have been packed or distributed by, such other drug manufacturer, processor, packer or distributor.

- (g) The term *device* (except when used in Paragraph (o) of this Section and in §§ 40103(k), 40110(f), 40115(c) and (o) and 40119(c) means instruments, apparatus and contrivances, including their components, parts and accessories, intended:
  - (1) For use in the diagnosis, cure, mitigation, treatment or prevention of disease in man or other animals; or
  - (2) To affect the structure or any function of the body of man or other animals.
  - (h) The term cosmetic means:
  - (1) Articles intended to be rubbed, poured, sprinkled or sprayed on, introduced into or otherwise applied to the human body or any part thereof for cleansing, beautifying, promoting attractiveness or altering the appearance; and
  - (2) Articles intended for use as a component of any such articles, except that such term shall not include soap.
- (i) The term *official compendium* means the official United States Pharmacopoeia, official Homeopathic Pharmacopoeia of the United States, official National Formulary or any supplement to any of them.
- (j) The term *consumer commodity*, except as otherwise specifically provided by this Subsection, means any food, drug, device or cosmetic as these terms are defined by this Act or by the Federal Act. Such term does not include:
  - (1) Any tobacco or tobacco product;
  - (2) Any commodity subject to packaging or labeling requirements imposed under the Guam Purchasing and Labeling Law (the Federal Insecticide, Fungicide and Rodenticide Act) or the provisions of the eighth paragraph under the heading "Bureau of Animal Industry" of the Act of March 4, 1913 (37 Stat. 832-833; 21 U.S.C. 151-157), commonly known as the Virus-Serum Toxin Act;
  - (3) Any drug subject to the provisions of \$40116(a) or (b), or \$40115(k) of this Act, or \$503(b)(1) or \$506 of the Federal Act;
  - (4) Any beverage subject to or complying with packaging or labeling requirements imposed under the Federal Alcohol Administration Act (27 U.S.C., et seq.); or

- (5) Any commodity subject to the provisions of the Federal Seed Act (7 U.S.C. 1551-1610).
- (k) The term *label* means a display of English language written or printed or graphic matter upon the immediate container of any article; and a requirement made by or under authority of this Act that any word, statement or other information appear on the label shall not be considered to be complied with unless such word, statement or other information also appears on the outside container or wrapper, if any there be, of the retail package of such article, or is easily legible through the outside container or wrapper.
- (1) The term *principal display panel* means that part of a label that is most likely to be displayed, presented, shown or examined under normal and customary conditions of display for retail sale.
  - (m) The term container does not includes package liners.
- (n) The term *package* means any container or wrapping in which any consumer commodity is enclosed for use in the delivery or display of that consumer commodity to retail purchasers, but does not include:
  - (1) Shipping containers or wrapping used solely for the transportation of any consumer commodity in bulk or in quantity to manufacturers, packers or processors or to wholesale or retail distributors thereof:
  - (2) Shipping containers or outer wrappings used by retailers to ship or deliver any commodity to retail customers if such containers and wrappings bear no printed matter pertaining to any particular commodity.
- (o) The term *labeling* means all labels and other English language written, printed or graphic matter:
  - (1) Upon an article or any of its containers or wrappers; or
  - (2) Accompanying such article.
- (p) The term *advertisement* means all representations disseminated in any manner or by any means, other than by labeling, for the purpose of inducing, or which are likely to induce, directly or indirectly, the purchase of food, drugs, devices or cosmetics.
- (q) The representation of a drug, in its labeling or advertisement, as an antiseptic shall be considered to be a representation that it is a germicide,

except in the case of a drug purporting to be, or represented as, an antiseptic for inhibitory use as a wet dressing, ointment, dusting powder or such other use as involves prolonged contact with the body.

#### (r) The term new drug means:

- (1) Any drug the composition of which is such that such drug is not generally recognized, among experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, as safe and effective for use under the conditions prescribed, recommended or suggested in the labeling thereof; or
- (2) Any drug the composition of which is such that such drug, as a result of investigations to determine its safety and effectiveness for use under such conditions, has become so recognized, but which has not, otherwise than in such investigations, been used to a material extent or for a material time under such conditions.
- (s) The term *contaminated with filth* applies to any food, drug, device or cosmetic not securely protected from dust, dirt or bacteria, and as far as may be necessary by all reasonable means, from all foreign or injurious contaminations.
- (t) The provisions of this Act regarding the selling of food, drugs, devices or cosmetics shall be considered to include the manufacture, production, processing, packing, exposure, offer, possession and holding of any such article for sale; and the sale, dispensing and giving of any such article, and the supplying or applying of any such articles in the conduct of any food, drug or cosmetic establishment.
- (u) The term *pesticide chemical* means any substance which, alone, in chemical combination, or in formulation with one or more other substances is an "economic poison" within the meaning of (the Federal Insecticide, Fungicide and Rodenticide Act, 7 U.S.C. §§135-135K, as now enacted or as hereafter amended) and which is used in the production, storage or transportation of raw agricultural commodities.
- (v) The term raw agricultural commodity means any food in its raw or natural state, including all fruits that are washed, colored or otherwise treated in their unpeeled natural form prior to marketing.
- (w) The term *food additive* means any substance, the intended use of which results or may be reasonably expected to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristics of

any food (including any substance intended for use in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting or holding food; and including any source of radiation intended for any such use) if such substance is not generally recognized, among experts qualified by scientific training and experience to evaluate its safety, as having been adequately shown through scientific procedures (or, in the case of a substance used in a food prior to January 1, 1958, through either scientific procedures or experience based on common use in food) to be safe under the conditions of its intended use; except that such term does not include:

- (1) A pesticide chemical in or on a raw agricultural commodity; or
- (2) A pesticide chemical to the extent that it is intended for use or is used in the production, storage or transportation of any raw agricultural commodity; or
  - (3) A color additive; or
- (4) Any substance used in accordance with a sanction or approval granted prior to the enactment of the Food Additives Amendment of 1958, pursuant to the Federal Act; the Poultry Products Inspection Act (21 U.S.C. 541 et. seq.) or the Meat Inspection Act of March 4, 1907 (34 Stat. 1260), as amended and extended (21 U.S.C. 71 et. seq.).
- (x) (1) The term *color additive* means a material which (a) is a dye, pigment or other substance made by a process of synthesis similar artificer, or extracted, isolated or otherwise derived, with or without intermediate or final change of identity, from a vegetable, animal, mineral or other source; or (b) when added or applied to a food, drug or cosmetic, or to the human body or any part thereof, is capable (alone or through reaction with other substance) or imparting color thereto; except that such term does not include any material which has been or hereafter is exempted under the Federal Act.
  - (2) The term *color* includes black, white and intermediate grays.
- (3) Nothing in clause (1) of Section 2 (x) shall be construed to apply to any pesticide chemical, soil or plant nutrient, or other agricultural chemical solely because of its effect in aiding, retarding or otherwise affecting, directly or indirectly, the growth or other natural

physiological process of produce of the soil and thereby affecting its color, whether before or after harvest.

- (y) The term *Federal Act* means the Drug and Cosmetic Act (Title 21 U.S.C. 301 et. seq.) and the Federal Fair Packaging and Labeling Act.
- (z) The term *pull date* means the calendar date printed by the manufacturer on the package or wrapping which represents the date after which the manufacturer recommends that the product not be sold:
  - (aa) The term *pack date* means the complete date (month in letters, day and year in numbers) printed by the manufacturer on the package, which represents the date the product has been produced and packaged.

SOURCE: GC § 9720.1, as amended by P.L. 14-17.

#### § 40103. Prohibited Acts.

The following acts and the causing thereof within the territory of Guam are hereby prohibited:

- (1) The manufacture, sale or delivery, holding or offering for sale of any food, drug, device or cosmetic that is adulterated or misbranded;
- (2) The adulteration or misbranding of any food, drug, device or cosmetic, except that, in the case of a food for which the pull date has expired, it may be sold, provided that a sign or notice clearly expressing the fact that the pull date has expired is placed in a conspicuous place next to the items in such a manner as to clearly inform the consumer as to the affected commodities:
- (3) The receipt in commerce of any food, drug, device or cosmetic that is adulterated or misbranded, and the delivery or proffered delivery thereof for pay or otherwise;
- (4) The distribution in commerce of a consumer commodity if such commodity is contained in a package, or if there is affixed to that commodity a label, which does not conform to the provisions of this Chapter and of regulations promulgated under authority of this Chapter; provided, however, that this prohibition shall not apply to persons engaged in business as wholesale or retail distributors of consumer commodities except to the extent that such persons:
  - (i) are engaged in the packaging or labeling of such commodities; or

- (ii) prescribe or specify by any means the manner in which such commodities are packaged or labeled;
- (5) The sale, delivery for sale, holding for sale, or offering for sale of any article in violation of §\$40111 or 40117;
  - (6) The dissemination of any false advertisement;
- (7) The refusal to permit entry or inspection, or to permit the taking of a sample, or to permit access to or copying of any record as authorized by \$40123:
  - (8) The giving of a guaranty or undertaking which is false;
- (9) The removal or disposal of a detained or embargoed article in violation of \$40106;
- (10) The alteration, mutilation, destruction, obliteration or removal of the whole or part of the labeling of, or the doing of any other Act with respect to a food, drug, device or cosmetic, if such act is done while such article is held for sale and results in such article being adulterated or misbranded:
- (11) Repackaging of food, drugs or cosmetics unless the repackaged product conforms to all labeling requirements set out in this Act;
- (12) Forging, counterfeiting, simulating or falsely representing, or without proper authority using any mark, stamp, tag, label or other identification device, authorized or required by regulations promulgated under the provisions of this Chapter or of the Federal Act;
- (13) The using by any person to his own advantage, or revealing, other than to the Consumer Counsel or his authorized representative or to the Courts when relevant in any judicial proceeding of any information acquired under authority of this Chapter concerning any method or process which as a trade secret is entitled to protection;
- (14) The using, on the labeling of any drug or in any advertisement relating to such drug, or any representation or suggestion that an application with respect to such drug is effective under \$40117, or that such drug complies with the provisions of such Section;
- (15) In the case of a prescription drug distributed or offered for sale in this Territory, the failure of the manufacturer, packer or distributor thereof to maintain for transmittal or to transmit, to any practitioner licensed by applicable law to administer such drug who makes written request for

information as to such drug, true and correct copies of all printed matter which is required to be included in any package in which that drug is distributed or sold, or such other printed matter as is approved under the Federal Act. Nothing in this Paragraph shall be construed to exempt any person from labeling requirements imposed by or under other provisions of this Chapter;

- (16) (i) Placing or causing to be placed upon any drug or device or container thereof, with intent to defraud, the trade name or other identifying mark, or imprint of another or any likeness of any of the foregoing; or
- (ii) Selling, dispensing, disposing of or causing to be sold, dispensed of, or disposed of, or concealing or keeping in possession, control or custody, with intent to sell, dispense or dispose of any drug, device or any container thereof, with knowledge that the trade name or other identifying mark or imprint of another or any likeness of any of the foregoing has been placed thereon in a manner prohibited by Paragraph (i) hereof; or
- (iii) Making, selling or disposing of, causing to be made, sold or disposed of, keeping in possession, control or custody, or concealing any punch, die, plate, stone or other thing designed to print, imprint or reproduce the trademark, trade name or other identifying mark, imprint or device of another, or any likeness of any of the foregoing upon any drug or container or labeling thereof so as to render such drug a counterfeit drug;
- (17) The doing of any act which causes a drug to be a counterfeit drug, or the sale or dispensing, or the holding for sale or dispensing of counterfeit drug;
- (18) Dispensing or causing to be dispensed a different drug or brand of drug in place of the drug or brand of drug ordered or prescribed without the express permission in each case of the person ordering or prescribing.

**SOURCE**: GC § 9720.2.

#### § 40104. Jurisdiction.

In addition to the remedies hereinafter provided, the Consumer Counsel or Director is hereby authorized to apply to the Superior Court for, and such Court shall have jurisdiction upon hearing and for cause shown, to grant a temporary or permanent injunction restraining any person from

violating any provision of §40103; irrespective of whether or not there exists an adequate remedy at law.

**SOURCE:** GC § 9720.3, as amended by P.L. 15-96.

#### § 40105. Penalty.

- (a) Any person who violates any of the provisions of \$40103 shall be guilty of a misdemeanor.
- (b) No person shall be subject to the penalties of Subsection (a) of this Section, for having violated Section 3(a) or (c) if he establishes a guaranty or undertaking signed by, and containing the name and address of, the person residing in the territory of Guam from whom he received in good faith the article, to the effect that such article is not adulterated or misbranded within the meaning of this Act, designated this Act.
- (c) No publisher, radio-broadcast licensee or agency or medium for the dissemination of an advertisement, except the manufacturer, packer, distributor or seller of the article to which a false advertisement relates, shall be liable under this Section for the dissemination of such false advertisement.

SOURCE: GC § 9720.4, as amended by P.L. 13-187.

**NOTE:** Subsection (b) appears here as in the original P.L. 13-143. See note to §40115.

#### § 40106. Tags for Adulterated Articles; Violations.

- (a) Whenever a duly authorized agent of the Director finds or has probable cause to believe that any food, drug, device, cosmetic or consumer commodity, as defined by this Act, is adulterated or so misbranded as to be dangerous or fraudulent, within the meaning of this Act or is in violation of \$\$40111 or 40117 of this Act, he shall affix to such articles a tag or other appropriate marking giving notice that such article is or is suspected of being adulterated or misbranded and has been detained or embargoed, and warning all persons not to remove or dispose of such article by sale or otherwise until permission for removal or disposal is given by an authorized agent of the Director or the Court. It shall be unlawful for any person to remove or dispose of such detained or embargoed article by sale or otherwise without such permission.
- (b) When an article is adulterated or misbranded or is in violation of §\$40111 or 40117 of this Act it shall be liable to be proceeded against by petition of the judge of the Court for libel for condemnation of such article.

When an authorized agent has found that an article which is embargoed or detained is not adulterated or misbranded, he shall remove the tag or other marking.

- (c) If the Court finds that a sampled, detained or embargoed article is adulterated or misbranded, such article shall, after entry of the decree, be destroyed at the expense of the owner thereof under the supervision of an authorized agent, and all Court costs and fees, storage and other proper expenses shall be taxed against the owner of such article or his agent; provided, that when the adulteration or misbranding can be corrected by proper labeling or processing of the article, the Court, after entry of the decree and after such costs, fees and expenses have been paid and a good and sufficient bond, conditioned that such article shall be so labeled or processed has been executed, may be order direct that such article be delivered to the owner thereof for such labeling or processing under the supervision of an agent of the Director. The expense of such supervision shall be paid by the owner. The article shall be returned to the owner and the bond shall be discharged on the representation to the Court by the Director that the article is no longer in violation of this Act and that the expenses for such supervision have been paid.
- (d) Whenever the Director or any of his authorized agents shall find in any room, building, vehicle of transportation or other structure, any meat, seafood, poultry, vegetable, fruit or other perishable articles which are unsound or contain any filthy, decomposed or putrid substance or that may be poisonous or deleterious to health or otherwise unsafe, the same being hereby declared to be a nuisance, the Director of his authorized agent shall forthwith condemn or destroy the same or in any other manner render the same unsalable as human food.

**SOURCE:** GC § 9720.5, as amended by P.L. 15-96.

#### § 40107. Institution of Proceedings.

It shall be the duty of the Director to cause appropriate proceedings to be instituted in the proper courts without delay and to be prosecuted in the manner required by law. Before the institution of a criminal proceeding, the person against whom such proceeding is contemplated shall be given appropriate notice and an opportunity to present his views before the Director or his designated agent, either orally or in writing, in person or by attorney, with regard to such contemplated proceeding.

**SOURCE:** GC § 9720.6.

#### § 40108. Regulations under Federal Act Apply.

- (a) Definitions and standards of identity, quality and fill of container and their amendments, now or hereafter adopted under authority of the Federal Act are the definitions and standards of identity, quality and fill of container in this Territory. However, when in his judgment such action will promote honesty and fair dealing in the interest of consumers, the Director may promulgate regulations establishing definitions and standards of identity, quality and fill of container for foods where no Federal regulations exist. In addition, the Director may promulgate amendments to any Federal or local regulations which set definitions and standards of identity, and may promulgate amendments to any Federal or local regulations which set standards of quality and fill of container for foods.
- (b) Temporary permits now or hereafter granted for import of experimental packs of food varying from the requirements of Federal definitions and standards of identity are automatically effective in this Territory under the conditions provided in such permits. In addition, the Director may issue additional permits where they are necessary to the completion of conclusiveness of an otherwise adequate investigation and where the interests of consumers are safeguarded. Such permits are subject to the terms and conditions the Director may prescribe by regulation.

**SOURCE:** GC § 9720.7.

#### § 40109. Adulterated Food.

A food shall be deemed to be adulterated:

- (1) If it bears or contains any poisonous or deleterious substance which may render it injurious to health; but in case the substance is not an added substance such food shall not be considered adulterated under this clause if the quantity of such substance in such food does not ordinarily render it injurious to health;
  - (2) (A) if it bears or contains any added poisonous or added deleterious substance, other than one which is (i) a pesticide chemical in or on a raw agricultural commodity; (ii) a food additive; or (iii) a color additive, which is unsafe within the meaning of Section 14(a); or
  - (B) if it is a raw agricultural commodity and it bears or contains a pesticide chemical which is unsafe within the meaning of the Federal Act; or

- (C) if it is or it bears or contains any food additive which is unsafe within the meaning of the Federal Act provided, that where a pesticide chemical has been used in or on a raw agricultural commodity in conformity with an exemption granted or tolerance prescribed by the Federal Act and such raw agricultural commodity has been subjected to processing such as canning, cooking, freezing, dehydrating or milling, the residue of such pesticide chemical remaining in or on such processed food shall, notwithstanding the provisions of §40113 and clause (C) of this Paragraph not be deemed unsafe if such residue in or on the raw agricultural commodity has been removed to the extent possible in good manufacturing practice, and the concentration of such residue in the processed food when ready-to-eat is not greater than the tolerance prescribed for the raw agricultural commodity;
- (3) If it consists in wholly or in part of a diseased, contaminated, filthy, putrid or decomposed substance, or if it is otherwise unfit for food;
- (4) If it has been produced, prepared, packed or held under insanitary conditions whereby it may have become contaminated with filth or whereby it may have been rendered diseased, unwholesome or injurious to health;
- (5) If it is, in whole or in part, the product of a diseased animal or of an animal which has died otherwise than by slaughter, or of an animal that has been fed upon the uncooked offal from a slaughterhouse;
- (6) If its container is composed, in whole or in part, of any poisonous or deleterious substance which may render the contents injurious to health;
- (7) If it has been intentionally subjected to radiation, unless the use of the radiation was in conformity with a regulation or exemption in effect pursuant to \$40113 of this Act or \$409 of the Federal Act;
- (8) If any valuable constituent has been in whole or in part omitted or abstracted therefrom;
  - (9) If any substance has been substituted wholly or in part therefor;
  - (10) If damage or inferiority has been concealed in any manner;
- (11) If any substance has been added thereto or mixed or packed therewith so as to increase its bulk or weight, or reduce its quality of strength or make it appear better or of greater value than it is;

- (12) If it is confectionery, and (i) has partially or completely imbedded therein any non-nutritive object; provided, that this clause shall not apply in the case of any non-nutritive objective if in the judgment of the Director as provided by regulations, such object is of practical functional value to the confectionery product and would not render the product injurious or hazardous to health; (ii) bears or contains any alcohol other than alcohol not in excess of one-half of the one percent (1/2 of 1%) by volume derived solely from the use of flavoring extracts; or (iii) bears or contains any nonnutritive substance; provided, that this clause shall apply to a safe nonnutritive substance which is in or on confectionery by reason of its use for some practical functional purpose in the manufacture, packaging or storing of such confectionery if the use of the substance does not promote deception of the consumer or otherwise result in adulteration or misbranding in violation of any provision of this Act; and provided further, that the Director may, for the purpose of avoiding or resolving uncertainty as to the application of this clause, issue regulations allowing or prohibiting the use of particular non-nutritive substances.
- (13) If it is or bears or contains any color additive which is unsafe within the meaning of the Federal Act; or
  - (14) If the product has a *pull date* on the packaging which has expired. **SOURCE:** GC § 9720.8.

**NOTE:** Subsection (2)(A)(iii) appears here as in the original P.L. 13-143. See Note to \$40115.

#### § 40110. Misbranded Food.

A food shall be deemed to be misbranded:

- (1) If its labeling is false or misleading in any particular;
- (2) If its labeling or packaging fails to conform with the requirements of \$40120 of this Act;
  - (3) If it is offered for sale under the name of another food;
- (4) If it is an imitation of another food unless its label bears in type of uniform size and prominence the word, *imitation*, and, immediately thereafter, the name of the food imitated;
  - (5) If its container is so made, formed or filled as to be misleading;
- (6) If in package form, unless it bears a label containing (i) the name and place of business of the manufacturer, packer or distributor; (ii) an

accurate statement of the net quantity of the contents in terms of weight, measure or numerical count, which statement shall be separately and accurately stated in a uniform location upon the principal display panel of the label; provided, that under clause (ii) of this Paragraph reasonable variations shall be permitted, and exemptions as to small packages shall be established by regulations prescribed by the Director;

- (7) If any word, statement or other information required by or under authority of this Act to appear on the label or labeling is not prominently placed thereon with such conspicuousness (as compared with other words, statements, designs or devices in the labeling) and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use;
- (8) If it purports to be or is represented as food for which a definition and standard of identity has been prescribed by regulations as provided by §40118, unless (i) it conforms to such definition and standard, and (ii) its label bears the name of the food specified in the definition and standards, and, insofar as may be required by such regulations, the common names of optional ingredients (other than spices, flavoring and coloring) present in such food;
- (9) If it purports to be or is represented as: (i) a food for which a standard of quality has been prescribed by regulations as provided by §40108, and its quality falls below such standard, unless its label bears, in such manner and form as regulations specify, a statement that it falls below such standard; or (ii) a food for which a standard or standards of fill of container have been prescribed by regulation as provided by §40108, and it falls below the standard of fill of container applicable thereto, unless its label bears, in such manner and form as such regulations specify, a statement that it falls below such standard:
- (10) If it is not subject to the provisions of Paragraph (8) of this Section unless it bears labeling clearly giving (i) the common or usual name of the food, if any there be and (ii) in case it is fabricated from two or more ingredients, the common or usual name of each such ingredient; except that spices, flavorings and colorings, other than those sold as such may be designated as spices, flavorings and colorings, without naming each; provided, that to the extent that compliance with the requirements of clause (ii) of this Paragraph is impractical or results in deception or unfair competition, exemptions shall be established by regulations promulgated by the Director;

- (11) If it purports to be or is represented for special dietary uses, unless its labels bears such information concerning its vitamin, mineral and other dietary properties as the Director determines to be, and by regulations prescribes as, necessary in order to fully inform purchasers as to its value for such uses:
- (12) If it bears or contains any artificial flavoring, coloring or chemical preservative, unless it bears labeling stating that fact; provided, that to the extent that compliance with the requirements of this Paragraph is impracticable, exemptions shall be established by regulations promulgated by the Director. The provisions of this Paragraph and Paragraphs (8) and (10) with respect to artificial coloring do not apply to butter, cheese or ice cream. The provisions of the paragraph with respect to chemical preservatives do not apply to a pesticide chemical when used in or on a raw agricultural commodity which is the produce of the soil;
- (13) If it is a raw agricultural commodity bearing or containing a pesticide chemical applied after harvest, unless the shipping container of such commodity bears labeling which declares the presence of such chemical in or on such commodity and the common or usual name and the function of such chemical; provided, however, that no such declaration shall be required while such commodity, having been removed from the shipping container, is being held or displayed for sale at retail out of such container in accordance with the custom of the trade;
- (14) If it is a product intended as an ingredient of another food and when used according to the directions of the purveyor will result in the final food product being adulterated or misbranded; or
- (15) If it is a color additive unless its packaging and labeling requirements applicable to such color additive prescribed under the provisions of the Federal Act.
- (16) If any locally packaged and/or processed food bears no calendar date indicating the pack date" written in English and which is easily legible and visible to the consumer.

**SOURCE:** GC § 9720.9, as amended by P.L. 14-17.

#### § 40111. Imports.

(a) The owner or consignee of each import shipment of any article subject to the provisions of this Chapter, shall furnish to the Director, at least seven (7) working days prior to importation, accurate information with

respect to the identity, quantity and value, source and origin, ownership, location of the import shipment and any other pertinent information needed or required by regulation to be promulgated by the Director.

- (b) The Director, Customs & Quarantine Agency, shall deliver to the Director, upon his request, samples of food, drugs, devices and cosmetics which are being imported or offered for import into Guam, giving notice thereof to the owner or consignee, who may appear before the Director and have the right to introduce testimony. The Director shall furnish to the Customs & Quarantine Agency a list of establishments registered in accordance with Subsection (i) of \$510 of the Federal Act, and shall request that if any drugs manufactured, prepared, propagated, compounded or processed in an establishment not so registered are imported or offered for import into Guam, samples of such drugs be delivered to the Director with notice of such delivery to the owner of consignee, who may appear before the Director and have the right to introduce testimony. If it appears from the examination of such samples of food, drugs, devices and cosmetics, or otherwise that (1) such article has been manufactured, processed or packed under insanitary conditions, or (2) such article is forbidden or restricted in sale in the country in which it was produced or from which it was exported, or (3) such article is adulterated, misbranded or is in violation of \$40117 of this Chapter, then such article shall be refused admission, except as provided in Subsection (c) of this Section. The Customs & Quarantine Agency shall cause the destruction of any such article refused admission unless such article is exported under regulations prescribed by the Customs & Quarantine Agency within ninety (90) days of the date of the notice such refusal or within such additional time as may be permitted pursuant to such regulations. This Paragraph shall not be construed to prohibit the admission of narcotic drugs, the importation of which is permitted under the Guam Uniform Controlled Substances Act.
- (c) Pending decision as to the admission of an article being imported or offered for import, the Custopms & Quarantine Agency may authorize delivery of such article to the owner or consignee upon the execution by him of a good and sufficient bond providing for the payment of such liquidated damages in the event of default as may be required pursuant to the regulations of the Customs & Quarantine Agency. If it appears to the Director that an article included within the provisions of clause (3) of Subsection (a) of this Section can, by relabeling or other action, be brought into compliance with this Chapter or rendered other than a food, drug, device or cosmetic, final determination as to admission of such article may

be deferred and, upon filling of timely written application by the owner or consignee and the execution by him of a bond as provided in the preceding provisions of this Subsection, the Director may in accordance with regulations, authorize the applicant to perform such relabeling or other action specified in such authorization (including destruction or export of rejected articles or portions thereof, as may be specified in the Director's authorization). All such relabeling or other action pursuant to such authorization shall in accordance with regulations be under the supervision of an officer or employee of the Department of Public Health and Social Services designated by the Director or an officer or employee of the Department of Commerce, Customs and Quarantine designated by the Director of that Department.

(d) All expenses (including travel, per diem or subsistence, and salaries of officers or employees of the government of Guam) in connection with the destruction provided for in Subsection (b) of this Section and the supervision of the relabeling or other action authorized under the provisions of Subsection (c) of this Section, the amount of such expenses to be determined in accordance with regulations, and all expenses in connection with the storage, cartage or labor with respect to any article refused admission under Subsection (b) of this Section, shall be paid by the owner or consignee and in default of such payment shall constitute a lien against any future importations made by such owner or consignees.

**SOURCE:** GC § 9720,10.

**NOTE:** The Legislature has separated Customs & Quarantine from the Department of Commerce. See 5 GCA Chapter 73.

#### § 40112. Exemptions from Labeling Requirement.

The Director shall promulgate regulations exempting from any labeling requirement of this Act food which is, in accordance with the practice of the trade, to be processed, labeled or repacked in substantial quantities at establishments other than those where originally processed or packed, on condition that such food is not adulterated or misbranded under the provisions of this Act upon removal from such processing, labeling or repacking establishment. Regulations now or hereafter adopted under authority of the Federal Act relating to such exemptions are automatically effective in this Territory. However, the Director may promulgate additional regulations or amendments to existing regulations concerning exemptions.

**SOURCE:** GC § 9720.11.

#### § 40113. Unsafe Substances.

- (a) Any added poisonous or deleterious substance, any food additive, any pesticide chemical in or on a raw agricultural commodity or any color additive, shall with respect to any particular use or intended use be deemed unsafe for the purpose of application of clause (2) of \$40109 with respect to any food, \$40114 with respect to any drug or device or \$40118 with respect to any cosmetic, unless there is in effect a regulation pursuant to \$40122 of this Act or Subsection (b) of this Section limiting the quantity of such substance, and the use or intended use of such substance conforms to the terms prescribed by such regulation. While such regulations relating to such substance are in effect, a food, drug or cosmetic shall not, by reason of bearing or containing such substance in accordance with the regulations, be considered adulterated within the meaning of clause (1), §\$40109, 40114 or 40118.
- (b) The Director, whenever public health or other considerations in this Territory so require, is authorized to adopt, amend or repeal regulations whether or not in accordance with regulations promulgated under the Federal Act, prescribing therein tolerances for any added, poisonous or deleterious substances, for food additives, for pesticide chemicals in or on raw agricultural commodities, or for color additives, including, but not limited to, zero tolerances and exemptions from tolerances in the case of pesticide chemicals in or on raw agricultural commodities, and prescribing the conditions under which a food additive or a color additive may be safely used and exemptions where such food additive or color additive is to be used solely for investigational or experimental purposes, upon his own motion or upon the petition of any interested party requesting that such a regulation be established. It shall be incumbent upon such petitioner to establish by data submitted to the Director that a necessity exists for such regulations, and that its effect will not be detrimental to the public health. If the data furnished by the petitioner is not sufficient to allow the Director to determine whether such regulation should be promulgated, the Director may require additional data to be submitted and failure to comply with the request shall be sufficient grounds to deny the request. In adopting, amending or repealing regulations relating to such substances the Director shall consider among other relevant factors the following which the petitioner, if any, shall furnish:
  - (1) The name and all pertinent information concerning such substance including where available, its chemical identity and

composition, a statement of the conditions of the proposed use, including directions, recommendations and suggestions and including specimens of proposed labeling, all relevant data bearing on the physical or other technical effect and the quantity required to produce such effect:

- (2) The probable composition of any substance formed in or on a food, drug or cosmetic resulting from the use of such substance;
- (3) The probable consumption of such substance in the diet of man and animals taking into account any chemically or pharmacologically related substance in such diet;
- (4) Safety factors which, in the opinion of experts qualified by scientific training and experience to evaluate the safety of such substances for the use or uses for which they are proposed to be used, are generally recognized as appropriate for the use of animal experimentation data;
- (5) The availability of any needed practicable methods of analysis for determining the identity and quantity of (i) such substance in or on an article; (ii) any substance formed in or on such article because of the use of such substance; and (iii) the pure substance and all intermediates and impurities; and
- (6) Facts supporting a contention that the proposed use of such substance will serve a useful purpose.

SOURCE: GC § 9720.12.

#### § 40114. Adulterated Drugs.

A drug or device shall be deemed to be adulterated:

- (1) If it consists in whole or in part of any filthy, putrid or decomposed substance:
- (2) If it has been produced, prepared, packed or held under unsanitary conditions where by it may have been rendered injurious to health;
- (3) If it is a drug and the methods used in or the facilities or controls used for its manufacture, processing, packing or holding do not conform to or are not operated or administered in conformity with current good manufacturing practice to assure that such drug meets the requirements of this Act as to safety and has the identity and strength, and meets the quality and purity characteristics, which it purports or is represented to possess;

- (4) If it is a drug and its container is composed, in whole or in part, or any poisonous or deleterious substance which may render the contents injurious to health;
- (5) If it is a drug and it bears or contains for purposes of coloring only, a color additive which is unsafe within the meaning of the Federal Act;
- (6) If it is a color additive, the intended use of which in or on drugs is for purposes of coloring only, and is unsafe within the meaning of the Federal Act;
- (7) If it purports to be or is represented as a drug the name of which is recognized in an official compendium, and its strength differs from or its quality or purity falls below, the standard set forth in such compendium. Such determination as to strength, quality or purity shall be made in accordance with the tests or methods of assay set forth in such compendium, or in the absence of or inadequacy of such tests or methods of assay, those prescribed under authority of the Federal Act. No drug defined in an official compendium shall be deemed to be adulterated under this Paragraph because it differs from the standard of strength, quality or purity therefor set forth in such compendium, if its difference in strength, quality or purity from such standard is plainly stated on its label. Whenever a drug is recognized in both the United States Pharmacopoeia and the Homeopathic Pharmacopoeia of the United States it shall be subject to the requirements of the United States Pharmacopoeia unless it is labeled and offered for sale as a homeopathic drug, in which case it shall be subject to the provisions of the Homeopathic Pharmacopoeia of the United States and not to those of the United States Pharmacopoeia;
- (8) If it is not subject to the provisions of Paragraph (b) of this Section and its strength differs from or its purity or quality falls below, that which it purports or is represented to possess; or
- (9) If it is a drug and any substance has been (i) mixed or packed therewith so as to reduce its quality or strength; or (ii) substituted wholly or in part therefor.

SOURCE: GC § 9705.13.

#### § 40115. Misbranded Drugs.

A drug or device shall be deemed to be misbranded:

- (1) If its labeling is false or misleading in any particular, or if its labeling or packaging fails to conform with the requirements of §40120 of this Act:
- (2) If in package form unless it bears a label containing (i) the name and place of business of the manufacturer, packer or distributor; and (ii) an accurate statement of the quantity of the contents in terms of weight, measure or numerical count, which statement shall be separately and accurately stated in a uniform location upon the principal display panel of the label, except as exempted with respect to this clause by \$40102(i)(3) of this Act; provided, that under clause (ii) of this Paragraph reasonable variations shall be permitted, and exemptions as to small packages shall be allowed in accordance with regulations prescribed by the Consumer Counsel or issued under the Federal Act;
- (3) If any word, statement or other information required by or under authority of this Act to appear on the label or labeling is not prominently placed thereon with such conspicuousness (as compared with other words, statements, designs or devices in the labeling) and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use;
- (4) If it is for use by man and contains any quantity of the narcotic or hypnotic substance alpha-eucaine, barbituric acid, beta-eucaine, bramble, cannabis, carbromal, chloral, coca, cocaine, codeine, heroin, marihuana, morphine, opium, paraldehyde, peyote or sulfonmethane, or any chemical derivative of such substance, which derivative after investigation has been found to be and designated as habit forming, by regulations issued by the Director under this Act, or by regulations issued pursuant to \$502(d) of the Federal Act, unless its label bears the name and quantity or proportion of such substance or derivative and in juxtaposition therewith the statement Warning May be habit forming;

#### (5) If it is a drug, unless:

(A) its label bears, to the exclusion of any other non-proprietary name (except the applicable systematic chemical name or the chemical formula), (i) the established name as defined in Paragraph (6) of the drug, if such there be; and (ii) in case it is fabricated from two or more ingredients, the established name and quantity of each active ingredient, including the kind and quantity or proportion of any alcohol and also including, whether active or not, the established name

and quantity or proportion of any bromides, ether, chloroform, acetanilid, acetphenetidin, aminopyrine, antipyrine, atropine, hyoscine, hyoscyamine, arsenic, digitalis, digitalis glucoside, mercury, ouabain, strophanthin, strychnine, thyroid or any derivative or preparation of any such substances, contained therein; provided, that the requirement for stating the quantity of the active ingredients, other than the quantity of those specifically named in this Paragraph, shall apply only to prescription drugs; and

- (B) for any prescription drug the established name of such drug or ingredient as the case may be, on such label (and on any labeling on which a name for such drug or ingredient is used) is printed prominently and in type at least half as large as that used thereon for any proprietary name or designation for such drug or ingredient; and provided that to the extent that compliance with the requirements of clause (A)(ii) or clause (B) of this Subparagraph is impracticable, exemptions shall be allowed under regulations promulgated by the Director, or under the Federal Act;
- (6) As used in this Paragraph and Paragraph (5), the term "established name," with respect to a drug or ingredient thereof, means:
  - (A) the applicable official name designated pursuant to §508 of the Federal Act, or
  - (B) if there is no such name and such drug, or such ingredient, is an article recognized in an official compendium, then official title thereof in such compendium, or
  - (C) if neither clause (A) nor Clause (B) of this Subparagraph applies, then the common or usual name, if any, of such drug or of such ingredient; provided further, that where clause (B) of this Subparagraph applies to an article recognized in the United States Pharmacopoeia and in the Homeopathic Pharmacopoeia under different official titles, the official title used in the United States Pharmacopoeia shall apply unless it is labeled and offered for sale as a homeopathic drug, in which case the official title used in the Homeopathic Pharmacopoeia shall apply;
- (7) Unless its labeling bears (i) adequate directions for use, and (ii) such adequate warnings against use in those pathological conditions or by children where its use may be dangerous to health, or against unsafe dosage or methods or duration of administration or application, in such manner and

form, as are necessary for the protection of users; provided, that where any requirement of clause (i) of this Paragraph, as applied to any drug or device, is not necessary for the protection of the public health, the Director shall promulgate regulations exempting such drug or device from such requirements; provided further, that articles exempted under regulations issued under §502(f) of the Federal Act may also be exempt;

- (8) If it purports to be a drug the name of which is recognized in an official compendium, unless it is packaged and labeled as prescribed therein; provided, that the method of packing may be modified with the consent of the Director or if consent is obtained under the Federal Act. Whenever a drug is recognized in both the United States Pharmacopoeia and the Homeopathic Pharmacopoeia of the United States, it shall be subject to the requirements of the United States Pharmacopoeia with respect to packaging and labeling unless it is labeled and offered for sale as a homeopathic drug, in which case it shall be subject to the provisions of the Homeopathic Pharmacopoeia of the United States and not to those of the United States Pharmacopoeia; provided further, that in the event of inconsistency between the requirements of this Paragraph and those of Paragraph (5) as to the name by which the drug or its ingredients shall be designated, the requirements of Paragraph (e) shall prevail;
- (9) If it has been found by the Director or under the Federal Act to be a drug liable to deterioration, unless it is packaged in such form and manner, and its label bears a statement of such precautions, as the regulations issued by the Director or under the Federal Act require as necessary for the protection of public health;
- (10) If it is a drug and its container is so made, formed or filled as to be misleading (i) if it is an imitation of another drug; (ii) if it is offered for sale under the name of another drug;
- (11) If it is dangerous to health when used in the dosage, or with the frequency or duration prescribed, recommended or suggested in the labeling thereof;
- (12) If it is, or purports to be, or is represented as a drug composed wholly or partly of insulin, unless (i) it is from a batch with respect to which a certificate or release has been issued pursuant to \$506 of the Federal Act, and (ii) such certificate or release is in effect with respect to such drug;
- (13) If it is, or purports to be, or is represented as a drug composed wholly or partly of any kind of penicillin, streptomycin, chlortetracycline,

chloramphenicol, bacitracin or any other antibiotic drug, or any derivative thereof, unless (i) it is from a batch with respect to which a certificate or release has been issued pursuant to \$507 of the Federal Act, and (ii) such certificate or release is in effect with respect to such drug; provided, that this Paragraph shall not apply to any drug or class of drugs exempted by regulations promulgated under \$507(c) or (d) of the Federal Act. For the purpose of this Paragraph the term "antibiotic drug" means any drug intended for use by man containing any quantity of any chemical substance which is produced by microorganisms and which has the capacity to inhibit or destroy microorganisms in dilute solution (including, the chemically synthesized equivalent of any such substance);

- (14) If it is a color additive, the intended use of which in or on drugs is for the purpose of coloring only, unless its packaging and labeling are in conformity with such packaging and labeling requirements applicable to such color additive, prescribed under the provisions of §40113 or of the Federal Act:
- (15) In the case of any prescription drug distributed or offered for sale in this Territory unless the manufacturer, packer or distributor thereof includes in all advertisements and other descriptive printed matter issued or caused to be issued by the manufacturer, packer or distributor with respect to that drug a true statement of (i) the established name, as defined in Section 16(c)(2) of this Act, printed prominently and in type at least half as large as that used for any trade or brand name thereof, (ii) the formula showing quantitatively each ingredient of such drug to the extent required for labels under §502(c) of the Federal Act, and (iii) such other information in brief summary relating to side effects, contraindications and effectiveness as shall be required in regulations issued under the Federal Act;
- (16) If a trademark, trade name or other identifying mark, imprint or device of another or any likeness of the foregoing has been placed thereon or upon its container with intent to defraud; or
- (17) Drugs and devices which are in accordance with the practice of the trade, to be processed, labeled or repacked in substantial quantities at establishments other than those where originally processed or packed shall be exempt from any labeling or packaging requirements of this Act; provided, that such drugs and devices are being delivered, manufactured, processed, labeled, repacked or otherwise held in compliance with regulations issued by the Director or under the Federal Act.

**SOURCE:** GC § 9720.14.

NOTE: The reference in Subsection (15)(i) of this Section to "Section 16(c)(2) of this Act" indicates that an earlier draft of the bill which became P.L. 13-143 was numbered differently, and that the numbering was not changed when Government Code section numbers were added. This may also explain the provisions of §\$40105(b), 40116(a) and (c), and 40109(2)(A)(iii). Assuming that §40101 of this Chapter was Section 1 of the original bill, then the numbers referred to in the sections cited above would appear to correspond to numbers of sections in the Government Code as renumbered and included in this compilation, as follows:

Section 3(a) or (c)" as referred to in \$40105(b) would be \$40103(1) or (3), (note the subsection numbers have apparently been changed from alphabetical in the original bill to numerical in P.L. 13-143); "Section 14(a)" as referred to in \$40109(2)(A)(iii) would be \$40114(1); "Section 16(c)(2)" as referred to in this Section would be \$40117(a)(B), (note that P.L. 13-143, and consequently this Chapter, is not consistent in numbering subsections either alphabetically or numerically, with the result that renumbering or relettering one section would require renumbering and relettering of all cross-references in each Section.

#### § 40116. Habit-Forming Drugs; Toxic Drugs.

- (a) A drug intended for use by man which:
  - (A) is a habit-forming drug to which §40115(d) applies; or
- (B) because of its toxicity or other potentiality for harmful effect, or the method of its use, or the collateral measures necessary to its use is not safe for use except under the supervision of a practitioner licensed by law to administer such drug; or
- (C) is limited by an approved application under §505 of the Federal Act or Section 18 of this Act to use under the professional supervision of a practitioner licensed by law to administer such drug, shall be dispensed only (i) upon a written prescription of a practitioner licensed by law to administer such drug, or (ii) upon an oral prescription of such practitioner which is reduced promptly to writing and filed by the pharmacist, or (iii) by refilling any such written or oral prescription if such refilling is authorized by the prescriber either in the original prescription or by oral order which is reduced promptly to writing and filed by the pharmacist. If any prescription for such drug does not indicate the times it may be refilled, if any, such prescription may not be refilled unless, the pharmacist is subsequently authorized to do so by the practitioner. The act of dispensing a drug contrary to the provisions of this Paragraph shall be deemed to be an act which results in a drug being misbranded while held for sale.

- (b) Any drug dispensed by filling or refilling a written or oral prescription of a practitioner licensed by law to administer such drug shall be exempt from the requirements of \$40115, except Subsections (a)(i)(2) and (3), (k) and (1) and the packaging requirements of Subsections (g) and (h), if the drug bears a label containing the name and address of the dispenser, the serial number and date of the prescription or of its filling, the name of the prescriber and, if stated in the prescription the name of the patient, and the directions for use and cautionary statements, if any, contained in such prescription. This exemption shall not apply to any drugs dispensed in the course of the conduct of a business of dispensing drugs pursuant to diagnosis by mail, or to a drug dispensed in violation of Paragraph (a) of this Section.
- (c) The Director may, by regulation, remove drugs subject to \$40115(d) and Section 18 from the requirements of Paragraph (a) of this Section when such requirements are not necessary for the protection of the public health. Drugs removed from the prescription requirements of the Federal Act by regulations issued thereunder may also, by regulations issued by the Director, be removed from the requirement of Paragraph (a).
- (d) A drug which is subject to Paragraph (a) of this Section shall be deemed to be misbranded if at any time prior to dispensing its label fails to bear the statement *Caution: Federal Law Prohibits Dispensing Without Prescription* or *Caution: State Law Prohibits Dispensing Without Prescription*. A drug to which Paragraph (a) of this Section does not apply shall be deemed to be misbranded if at any time prior to dispensing its label bears the caution statement quoted in the preceding sentence.
- (e) Nothing in this Section shall be construed to relieve any person from any requirement prescribed by or under authority of law with respect to drugs now included or which may hereafter be included within the classifications of narcotic drugs or marihuana as defined in the applicable Federal and local laws relating to narcotic drugs and marihuana.

**SOURCE:** GC § 9720.15.

NOTE: Reference to "Section 18" appear here as in P.L. 13-143. See NOTE to §744.

#### § 40117. Sale of New Drugs.

(a) No person shall sell, deliver, offer for sale, hold for sale or give away any new drug unless (1) an application with respect thereto has been approved and said approval has not been withdrawn under §505 of the Federal Act, or (2) when not subject to the Federal Act, unless such drug has

been tested and has been found to be safe for use and effective in use under the conditions prescribed, recommended or suggested in the labeling thereof, and prior to selling or offering for sale such drug, there has been filed with the Director an application setting forth (i) full reports of investigations which have been made to show whether or not such drug is safe for use and whether such drug is effective in use; (ii) a full list of the articles used as components of such drug; (iii) a full statement of the composition of such drug; (iv) a full description of the methods used in, and the facilities and controls used for the manufacturer, processing and packing of such drug; (v) such samples of such drug and of the articles used as components thereof as the Director may require; and (vi) specimens of the labeling proposed to be used for such drug.

- (b) An application provided for in Subsection (a)(2) shall become effective on the one hundred eightieth day after the filing thereof, except that if the Director finds, after due notice to the applicant and giving him an opportunity for a hearing (1) that the drug is not safe or not effective for use under the conditions prescribed, recommended or suggested in the proposed labeling thereof; or (2) the methods used in and the facilities and controls used for the manufacturer, processing and packing of such drugs are inadequate to preserve its identity, strength, quality and purity; or (3) based on a fair evaluation of all material facts, such labeling is false or misleading in any particular; he shall, prior to the effective date of the application issue an order refusing to permit the application to become effective.
  - (c) Vacant.
- (d) The Director shall promulgate regulations for exempting from the operation of the foregoing Subsections of this Section drugs intended solely for investigational use by experts qualified by scientific training and experience to investigate the safety and effectiveness of drugs. Such regulations may, within the discretion of the Director among other conditions relating to the protection of the public health, provide for conditioning such exemption upon:
  - (1) the submission to the Director, before any clinical testing of a new drug is undertaken, of reports by the manufacturer or the sponsor of the investigation of such drug, of pre-clinical tests (including tests on animals) of such drug adequate to justify the proposed clinical testing;

- (2) the manufacturer or the sponsor of the investigation of a new drug proposed to be distributed to investigators for clinical testing obtaining a signed agreement from each of such investigators that patients to whom the drug is administered will be under his personal supervision, or under the supervision of investigators responsible to him and that he will not supply such drug to any other investigator or to clinics for administration to human beings; and
- (3) the establishment and maintenances of such records and the making of such reports to the Director by the manufacturer or the sponsor of the investigation of such drug of data (including but not limited to analytical reports by investigators) obtained as the result of such investigational use of such drug, as the Director finds will enable him to evaluate the safety and effectiveness of such drug in the event of the filing of an application pursuant to Subsection (b).

Such regulations shall provide that such exemption shall be conditioned upon the manufacturer, or the sponsor of the investigation, requiring that experts using such drugs for investigational purposes certify to such manufacturer or sponsor that they will inform any human beings to whom such drugs, or any controls used in connection therewith, are being administered, or their representatives, that such drugs are being used for investigational purposes and will obtain the consent of such human beings or their representatives, except where they deem it not feasible or, in their professional judgment, contrary to the best interests of such human beings. Nothing in this Subsection shall be construed to require any clinical investigator to submit directly to the Director reports on the investigational use of drugs; provided, that the regulations adopted under Section 505(i) of the Federal Act shall be the regulations in this Territory; provided further, that the Director may in his discretion promulgate regulations whether or not in accordance with regulations promulgated under the Federal Act.

(e)(1) In the case of any drug for which an approval of an application filed pursuant to this Section is in effect, the applicant shall establish and maintain such records and make such reports to the director of data relating to clinical experience and other data or information received or otherwise obtained by such applicant with respect to such drug, as the Director may by general regulation or by order with respect to such application prescribe; provided, however, that regulations and orders issued under this Subsection and under Subsection (d) shall have due regard for the professional ethics of the

medical profession and the interests of patients and shall provide, where the Director deems it to be appropriate, for the examination, upon request by the persons to whom such regulations or orders are applicable, of similar information received or otherwise obtained by the director.

- (2) Every person required under this Section to maintain records, and very person in charge or custody thereof, shall, upon request of an officer or employee designated by the Director, permit such officer or employee at all reasonable times to have access to and copy and certify such records.
- (f) The Director may, after affording an opportunity for public hearing and judicial appeal, revoke an application approved pursuant to this Section if he finds that the drug, based on evidence acquired after such approval, may not be safe or effective for its intended use or that the facilities or controls used in the manufacture, processing or labeling of such drug may present a hazard to the public health.

#### (g) This Section shall not apply:

- (1) to a drug sold in this Territory or introduced into interstate commerce at any time prior to the enactment of the Federal Act, if its labeling contained the same representations concerning the conditions of its use; or
- (2) to any drug which is licensed under the Public Health Service Act of July 1, 1944 (42 U.S.C. 201 et. seq.), or under the Animal Virus-Serum-Toxin Act of March 4, 1913 (13 Stat. 832; 21 U.S.C. 151 et. seq.); or
  - (3) to any drug which is subject to Section 16(1) of this Act.

SOURCE: GC § 9720.16.

NOTE: For explanation of Subsection (g)(3) see NOTE to §40115.

#### § 40118. Adulterated Cosmetics.

A cosmetic shall be deemed to be adulterated:

(1) If it bears or contains any poisonous or deleterious substance which may render it injurious to users under the conditions of use prescribed in the labeling or advertisement thereof, or under such conditions of use as are customary or usual; provided, that this provision shall not apply to coal-tar hair dye, the label of which bears the following legend conspicuously

displayed thereon: "Caution - This product contains ingredients which may cause skin irritation on certain individuals and a preliminary test according to accompanying directions should first be made. This product must not be used for dyeing the eyelashes or eyebrows; to do so may cause blindness," and the labeling of which bears adequate directions for such preliminary testing. For the purpose of the paragraph and Paragraph (c) the term "hair dye" shall not include eyelash dyes or eyebrow dyes;

- (2) If it consists in whole or in part of any filthy, putrid or decomposed substance;
- (3) If it has been produced, prepared, packed or held under insanitary conditions whereby it may have been rendered injurious to health;
- (4) If its container is composed, in whole or in part, of any poisonous or deleterious substance which may render the contents injurious to health; or
- (5) If it is not a hair dye and it is, or it bears or contains a color additive which is unsafe within the meaning of \$40113(a).

**SOURCE:** GC § 9720.17.

#### § 40119. Misbranded Cosmetics.

A cosmetic shall be deemed to be misbranded:

- (1) If its labeling is false or misleading in any particular;
- (2) If its labeling or packaging fails to conform with the requirements of §40120 of this Act;
- (3) If in package form unless it bears a label containing (i) the name and place of business of the manufacturer, packer or distributor; and (ii) an accurate statement of the quantity of the contents in terms of weight, measure or numerical count, which statement shall be separately and accurately stated in a uniform location upon the principal display panel of the label; provided, that under clause (ii) of this Paragraph reasonable variations shall be permitted, and exemption as to small packages shall be established by regulations prescribed by the Director;
- (4) If any word, statement or other information required by or under authority of this Act to appear on the label or labeling is not prominently placed thereon with such conspicuousness (as compared with other words, statements, designs or devices in the labeling) and in such terms as to render

it likely to be read and understood by the ordinary individual under customary conditions of purchase and use;

- (5) If its container is so made, formed or filled as to be misleading;
- (6) If it is a color additive, unless its packaging and labeling are in conformity with such packaging and labeling requirements applicable to such color additive prescribed under the provisions of the Federal Act. This Paragraph shall not apply to packages of color additives which, with respect to their use for cosmetics, are marketed and intended for use only in or on hair dyes (as defined in the last sentence of §40118(a)(1); or
- (7) A cosmetic which is, in accordance with the practice of the trade, to be processed, labeled or repacked in substantial quantities at an establishment other than the establishment where it was originally processed or packed, is exempted from the affirmative labeling requirements of this Act while it is in transit in commerce from the one establishment to the other, if such transit is made in good faith for such completion purposes only; but is otherwise subject to all applicable provisions of this Act.

**SOURCE:** GC § 9720.18.

#### § 40120. Labeling Requirements.

- (a) All labels of consumer commodities, as defined by this Act, shall conform with the requirements for the declaration of net quantity of contents of Section 4 of the Fair Packaging and Labeling Act (15 U.S.C. 1451, et. seq.) and the regulations promulgated pursuant thereto; provided, that consumer commodities exempted from such requirements of Section 4 of the Fair Packaging and Labeling Act shall also be exempt from this Subsection.
- (b) The label of any package of a consumer commodity which bears a representation as to the number of servings of such commodity contained in such package shall bear a statement of the net quantity (in terms of weight, measure or numerical count) of each such serving.
- (c) If an article is alleged to be misbranded because the labeling is misleading, or if an advertisement is alleged to be false because it is misleading, then in determining whether the labeling or advertisement is misleading, there shall be taken into account (among other things) not only representations made or suggested by statement, word, design, device, sound or in any combination thereof, but also the extent to which the labeling or advertisement fails to reveal facts material in the light of such

representations or material with respect to consequences which may result from the use of the article to which the labeling or advertisement relates under the conditions of use prescribed in the labeling or advertisement thereof or under such conditions of use as are customary or usual.

- (d) No person shall distribute or cause to be distributed in commerce any packaged consumer commodity if any qualifying words or phrases appear in conjunction with the separate statement of the net quantity of contents required by Subsection (a), but nothing in this Section shall prohibit supplemental statements, at other places on the package, describing in nondeceptive terms the net quantity of contents; provided, that such supplemental statements of net quantity of contents shall not include any term qualifying a unit of weight, measure or count that tends to exaggerate the amount of the commodity contained in the package.
- (e) Whenever the Director determines that regulations containing prohibitions or requirements other than those prescribed by Section 21(a) are necessary to prevent the deception of consumers or to facilitate value comparisons as to any consumer commodity, the Director shall promulgate with respect to that commodity regulations effective to:
  - (1) establish and define standards for the characterization of the size of a package enclosing any consumer commodity, which may be used to supplement the label statement of net quantity of contents of packages containing such commodity, but this Paragraph shall not be construed as authorizing any limitation on the size, shape, weight, dimensions or number of packages which may be used to enclose any commodity;
  - (2) regulate the placement upon any package containing any commodity or upon any label affixed to such commodity, of any printed matter stating or representing by implication that such commodity is offered for retail sale at a price lower than the ordinary retail sale price or that a retail sale price advantage is accorded to purchasers thereof by reason of the size of that package or the quantity of its contents;
  - (3) require that the label on each package of a consumer commodity bear (A) the common or usual name of such consumer commodity, if any, and (B) in case such consumer commodity consists of two or more ingredients, the common or usual name of each such ingredient listed in order of decreasing predominance, but nothing in

this Paragraph shall be deemed to require that any trade secret be divulged; or

(4) prevent the nonfunctional slack-fill of packages containing consumer commodities.

For the purpose of Paragraph (4) of Subsection (e), a package shall be deemed to be non functional slack-filled if it is filled of substantially less than its capacity for reasons other than (A) protection of the contents of such package or (B) the requirements of machines used for enclosing the contents in such package; provided, that the Director may adopt any regulations promulgated pursuant to the Fair Packaging and Labeling Act which shall have the force and effect of law in this Territory.

- (f) Any food, drug or consumer commodity for which the manufacturer or distributor has established or recommended a pull date or other date by which the food, drug or consumer commodity should be used shall:
  - (1) Have the *pull date*, "best if used by date, expiration date or other date by which the food, drug or consumer commodity should be used, clearly marked on the packaging or labeling. Color coding may be used if the meanings of the color codes are clearly and plainly displayed in close proximity to the consumer commodities. Any product with a date on it shall be clearly marked as to whether the date is the date of packaging, the pull date, the expiration date, or some other date.
  - (2) Any outdated food, drug or consumer commodity which is still fit for human consumption and which is more than two days outdated, may be sold, displayed in a retail store or offered for sale only if the item is still fit for human consumption and each package is clearly marked with the word "Outdated or "Expired Merchandise or such other words of similar meaning as may be approved by regulations promulgated by the Director of the Department of Public Health.
  - (3) Notwithstanding any provision of law, all fresh or frozen packaged meat, fresh eggs, bread, fresh milk and fresh daily products and ice cream, and such other food, drug and consumer commodity designated by the Director of the Department of Public Health and Social Services shall have a clearly designated expiration date on each package offered for retail sale. Notwithstanding any other provision of law, in lieu of stamping any required labels whatsoever on individual eggs, such information may instead be stamped on each egg carton if

the eggs are packed in individual cartons of twelve (12) eggs or less as required by 5 GCA Chapter 66, the *Chicken Egg Regulation*. (g) Any dented or damaged package or can of consumer products shall clearly be marked "*Damaged*.

- (h) Any fresh or frozen meat or poultry products which have had water added shall be clearly labeled "Water added. Any meat products which have been previously given a United States Department of Agriculture grade or category shall have the grade or category clearly marked on each package of meat offered for sale, whether or not later repackaged.
- (i) It shall be unlawful to sell any rusty canned goods or goods with rusty metal lids, unless the rust can be removed by rubbing with a cotton cloth.
- (j) It shall be a misdemeanor for any person to sell or offer for sale any food, drug or consumer commodity which is not clearly labeled and marked in English or Chamorro as herein provided for in this Chapter.
- (k) In addition to criminal penalties for the violation of this Section, the Director of Public Health and Social Services shall, by rules and regulations to be established seize and destroy all food, drug, or consumer products which are displayed or offered for sale which are not properly marked or labeled in the English or Chamorro languages, and shall pursuant to regulations, impose civil penalties and fines not exceed Five Hundred Dollars (\$500) for each failure to properly label or mark products in English or Chamorro languages as provided by this Chapter, and may, pursuant to regulation, and close repeated offenders; shall
- (1) In addition to any other penalties provided for by law, each violation of this Section shall be counted as at least one or more demerits as the conditions dictate, in determining demerit points in the issuance of sanitary permits or renewals thereof as provided for in 10 GCA Chapter 21. For purposes of this subsection, a minimum of one (1) demerit point must be given for each different inventory item found in violation of this Section, but exactly identical items found in violation may be counted as one violation.
- (m) Any seller of food, drugs and consumer commodities found to have more than twenty (20) different products displayed or offered for sale which do not comply with the provisions of this Section shall be immediately closed in the same manner as an unsanitary establishment pursuant to the provisions of 10 GCA Chapter 21.

authorized to make the regulations promulgated under this Act conform, insofar as practicable, with those promulgated under the Federal Act.

- (b) Hearings authorized or required by this Act shall be conducted by the Director or such officer, agent or employee as the Director may designate for the purpose.
- (c) All pesticide chemical regulations and their amendments now or hereafter adopted under authority of the Federal Food,

Drug and Cosmetic Act are the pesticide chemical regulations in this Territory.

- (d) All food additive regulations and their amendments now or hereafter adopted under authority of the Federal Food, Drug and Cosmetic Act are the food additive regulations in this Territory.
- (e) All color additive regulations and their amendments now or hereafter adopted under authority of the Federal Food, Drug and Cosmetic Act are the color additive regulations in this Territory.
- (f) All special dietary use regulations and their amendments now or hereafter adopted under authority of the Federal Food, Drug and Cosmetic Act are the special dietary use regulations in this Territory.
- (g) All regulations and their amendments now or hereafter adopted under the Fair Packaging and Labeling Act shall be the regulations in this Territory. However, the Director may, if he finds it necessary in the interest of consumers, prescribe packaging and labeling regulations for consumer commodities, whether or not in accordance with regulations promulgated under the Federal Act; provided, that no such regulations shall be promulgated which are contrary to the labeling requirements for the quantity of contents required pursuant to Section 4 of the Fair Packaging and Labeling Act and the regulations promulgated thereunder.
- (h) A Federal regulation automatically adopted pursuant to this Act takes effect in this Territory on the date it becomes effective as a Federal regulation. The Director shall publish all other proposed regulations in a newspaper of general daily circulation. A person who may be adversely affected by a regulation may, within thirty (30) days after publication of any other regulation, file with the Director in writing objections and a request for a hearing. The timely filing of substantial objections to a Federal regulation automatically adopted stays the effect of the regulation. If no substantial objections are received and no hearings are requested within 30

(thirty) days after publication of a proposed regulation, it shall take effect on a date set by the Director. The effective date shall be at least sixty (60) days after the time for filing objections has expired. If timely substantial objections are made to a Federal regulation within thirty (30) days after it is automatically adopted or to a proposed regulation within thirty (30) days after it is published, the Director after notice, shall conduct a public hearing to receive evidence on the issues raised by the objections.

Any interested person or his representative may be heard. The Director shall act upon objections by order and shall mail the order to objectors by certified mail as soon after the hearing as practicable. The order shall be based on substantial evidence in the record of the hearing. If the order concerns a Federal regulation, it may reinstate, rescind or modify it. If the order concerns a proposed regulation, it may withdraw it or set an effective date for the regulation as published or as modified by the order. The effective date shall be at least sixty (60) days after publication of the order.

**SOURCE:** GC § 9720.21.

### § 40123. Inspections.

- (a) For purposes of enforcement of this Act, the Director or any of his authorized agents, are authorized upon presenting appropriate credentials to the owner, operator or agent in charge:
  - (1) to enter at reasonable times any factory, warehouse or establishment in which food, drugs, devices or cosmetics are manufactured, processed or packed or held for introduction into commerce or after such introduction or to enter any vehicle being used to transport or hold such food, drugs, devices or cosmetics in commerce; and
  - (2) to inspect at reasonable times and within reasonable limits and in a reasonable manner such factory, warehouse, establishment or vehicle and all pertinent equipment, finished and unfinished materials, containers and labeling therein, and to obtain samples necessary to the enforcement of this Act. In the case of any factory, warehouse, establishment or consulting laboratory in which prescription drugs are manufactured, processed, packed or held, the inspection shall extent to all things therein (including records, files, papers, processes, controls and facilities) bearing on whether prescription drugs which are adulterated or misbranded within the meaning of this Act or which may not be manufactured, introduced into commerce or sold or offered for sale by reason of any provision of this Act, have been or are being

manufactured, processed, packed, transported or held in any such place or otherwise bearing on violation of this Act. No inspection authorized for prescription drugs by the preceding sentence shall extend to (A) financial data, (B) sales data other than shipment data, (C) pricing data, (D) personnel data (other than data as to the qualifications of technical and professional personnel performing functions subject to this Act), and (E) research data (other than data relating to new drugs and antibiotic drugs, subject to reporting and inspection under regulations lawfully issued pursuant to Section 505(i) or (j) or Section 507(d) and (g) of the Federal Act, and data, relating to other drugs, which in the case of a new drug would be subject to reporting or inspection under lawful regulations issued pursuant to Section 505(j) of the Federal Act). Such inspection shall be commenced and completed with reasonable promptness. The provisions of the second sentence of this Subsection shall not apply to:

- (i) pharmacies which maintain establishments in conformance with local laws regulating the practice of pharmacy and medicine and which are regularly engaged in dispensing prescription drugs, upon prescriptions of practitioners licensed to administer such drugs to patients under the care of such practitioners in the course of their professional practice and which do not, either through a subsidiary or otherwise, manufacture, prepare, propagate, compound or process drugs for sale other than in the regular course of their business of dispensing or selling drugs at retail;
- (ii) practitioners licensed by law to prescribe or administer drugs and who manufacture, prepare, propagate, compound or process drugs solely for use in the course of their professional practice;
- (iii) persons who manufacture, prepare, propagate, compound or process drugs solely for use in research, teaching or chemical analysis and not for sale;
- (iv) such other classes of persons as the Director may by regulation exempt from the application of this Section upon a finding that inspection as applied to such classes of persons in accordance with this Section is not necessary for the protection of the public health; and

- (3) to have access to and to copy all records of carriers in commerce showing the movement in commerce of any food, drug, device or cosmetics, or the holding thereof during or after such movement, and the quantity, shipper and consignee thereof; provided, that evidence obtained under this Subsection shall not be used in a criminal prosecution of the person from whom obtained; and provided further, that carriers shall not be subject to the other provisions of this Act by reason of their receipt, carriage, holding or delivery of food, drugs, devices or cosmetics in the usual course of business as carriers.
- (b) Upon completion of any such inspection of a factory, warehouse, consulting laboratory or other establishment and prior to leaving the premises, the authorized agent making the inspection shall give to the owner, operator or agent in charge a report in writing setting forth any conditions or practices observed by him which in his judgment indicate that any food, drug, device or cosmetic in such establishment (1) consists in whole or in part of any filthy, putrid or decomposed substance or (2) has been prepared, packed or held under insanitary conditions whereby it may have become contaminated with filth or whereby it may have been rendered injurious to health. A copy of such report shall be sent promptly to the Director.
- (c) If the authorized agent making any such inspection of a factory, warehouse or other establishment has obtained any sample in the course of the inspection, upon completion of the inspection and prior to leaving the premises, he shall give to the owner, operator or agent in charge a receipt describing the samples obtained.
- (d) When in the course of any such inspection of a factory or other establishment where food is manufactured, processed or packed, the officer or employee making the inspection obtains a sample of any such food and an analysis is made of such sample for the purpose of ascertaining whether such food consists in whole or in part of any filthy, putrid or decomposed substance or is otherwise unfit for food, a copy of the results of such analysis shall be furnished promptly to the owner, operator or agent in charge.

SOURCE: GC § 9720.22.

### § 40124. Report of Minor Violations.

Nothing in this Subchapter shall be construed as requiring the Director to report for the institution of proceedings under this Chapter, minor

violations of this Chapter, whenever the Director believes that the public interest will be adequately served in the circumstances by a suitable written notice or warning.

SOURCE: GC § 9720.23.

### § 40125. Emergency Permit Control.

- (a) Whenever the Director finds after investigation that the distribution in the territory of Guam of any class of food may, by reason of contamination with microorganism during manufacture, processing or packing thereof in any locality, be injurious to health and that such injurious nature cannot be adequately determined after such articles have entered commerce, he then, and in such case only, shall promulgate regulations providing for the issuance to manufacturers, processors or packers of such class of food in such locality of permits to which shall be attached such conditions governing the manufacture, processing or packing, or packing of such class of food, for such temporary period of time as may be necessary to protect the public health; and after the effective date of such regulations and during such temporary period, no person shall introduce or deliver for introduction into commerce any such food manufactured, processed or packed by any such manufacturer, processor or packer unless such manufacturer, processor or packer holds a permit issued by the Director as provided by such regulations.
- (b) The Director is authorized to suspend immediately upon notice any permit issued under authority of this Section if it is found that any of the conditions of the permit have been violated. The holder of a permit so suspended shall be privileged at any time to apply for reinstatement of such permit and the Director shall immediately after prompt hearing and inspection of the establishment, reinstate such permit if it is found that adequate measures have been taken to comply with and maintain the conditions of the permit, as originally issued or as amended.
- (c) Any officer or employee duly designated by the Director shall have access to any factory or establishment, the operator of which holds a permit from the Director for the purpose of ascertaining whether or not the conditions of the permit are being complied with and denial of access for such inspection shall be grounds for suspension of the permit until access is freely given by the operator.

**SOURCE:** GC § 9720.24.

§ 40126. Reports of Judgment and Decrees.

- (a) The Director shall cause to be published from time to time reports summarizing all judgments, decrees and court orders which have been rendered under this Act, including the nature of the charge and the disposition thereof.
- (b) The Director shall also cause to be disseminated such information regarding food, drugs, devices and cosmetics as the Director deems necessary in the interest of public health and the protection of the consumer against fraud. Nothing in this Section shall be construed to prohibit the Director from collecting, reporting and illustrating the results of the investigations of the Director.

**SOURCE:** GC § 9720.25.

### § 40127. Severability.

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If any provision of this Act is declared unconstitutional or the applicability thereof to any person or circumstances is held invalid, the constitutionality of the remainder of the Act and applicability thereof to other persons and circumstances shall not be affected thereby.

**SOURCE:** GC § 9720.26.

### § 40128. Effective Date.

The effective date of this legislation shall be one hundred eighty (180) days from the passage of this Act. Monthly reports of inspection, investigation and enforcement of this Act shall be made in a public newspaper of wide general circulation thereafter.

SOURCE: GC § 9720.27.

### § 40129. Authorization.

There is hereby authorized to be appropriated the sum of One Hundred One Thousand Two Hundred and Forty Dollars (\$101,240) to the Department of Public Health and Social Services, Bureau of Environmental Health and Consumer Protection for the implementation and administration of this Act.

**SOURCE:** GC § 9720.28.

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# Electronic Cigarettes and Guam Laws

### **SUMMARY**

### **ELECTRONIC CIGARETTES**

- Federal Tobacco Control Act imposed certain restrictions related to tobacco and authorized FDA to regulate tobacco.
- FDA's regulation of tobacco includes products "made or derived for tobacco" that are not drug or device.
- Because e-cigarettes are tobacco products (apparently it is derived from tobacco) and have not been proven to be a drug or a medical device, it too can be regulated by FDA.
- Since it is not a drug or a device, it has no medical use.
- FDA has yet to develop regulations for e-cigarettes.
- Locally, it cannot be regulated by DEH since it is not a drug or a device (Title 10 GCA, Chapter 40, Guam Food, Drug and Cosmetic Act).
- Amending Title 10 GCA, Chapter 90 (the indoor smoking law) may be a method to regulate ecigarettes on Guam.

### Latest News from FDA Action on E-Cigarettes

- It was two years ago when the Food and Drug Administration (FDA) said that it would propose rules on regulating electronic cigarettes, the agency still has not released any proposed rules.
- The FDA has set a target date of October 2013 to release its proposed rules to the public. The agency did get a proposed rule sent in mid-October to the federal Office of Management and Budget, which will review the rule before it is released for public comment. But the partial government shutdown in late September and early October could possibly cause the delay.
- A clarification letter was issued by FDA regarding an August 22, 2013 article in the Wall Street Journal, titled "FDA Discusses Banning Online Sales of E-Cigarettes" states that FDA did not raise any potential regulatory options or restrictions on e-cigarettes. This was posted in the FDA website last August 26, 2013, and shows the latest press release of FDA relative to electronic cigarettes.

### Guam Law

Based on the research on electronic cigarettes, Title 10 GCA, Chapter 40 of Guam Drug and Cosmetic Act is not applicable. On April 2011, an article to stakeholders from FDA stated that the FD&C Act, as amended by the Tobacco Control Act, defines the term "tobacco products," in part as any product "made or derived from tobacco" that is not a "drug," "device," or combination product under the FD&C Act. The smoke-free laws in Guam can be applied to limit the public's exposure to secondhand e-cigarette vapor. There is concern on the availability of e-cigarettes which may increase the incidence of young people smoking. Public Law 24-278, requires vendors of tobacco products to obtain a tobacco license and enforces the prohibition of sales of tobacco products to minors.

### Public Health Issue

E-cigarette products are produced by hundreds of largely overseas companies — with no regulation, no oversight, and no requirement for ingredient disclosure. Some studies have shown the presence of dangerous chemicals and a lack of quality control.

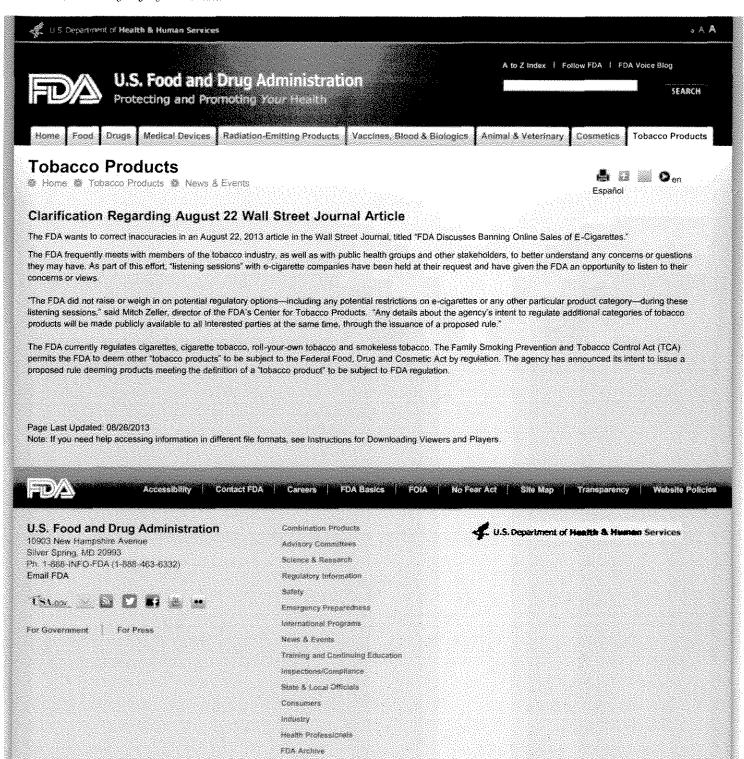
### References:

- 1. Accessed January 03, 2014, Letter of Clarification regarding August Wall Street Journal Article, available at www.fda.gov/Tobacco Products/NewsEvents/ucm366187
- 2. Letter of National Association of Attorneys General to FDA Commissioner September 24, 2013.

- 3. Letter of Association of State and Territorial Health Officials (ASTHO) to FDA Commissioner October 22, 2013.
- 4. Regulation of E-cigarettes and other Tobacco Products April 25, 2011
- 5. FDA Consumer Health Information July 2009.
- 6. Electronics cigarettes and related Guam laws on tobacco.
- 7. Electronic cigarettes as tobacco products April 28 2011.

# **ATTACHMENTS**

- A. Press Release of FDA Clarification Regarding
  August 22 Wall Street Journal Article
- B. Title 10 GCA Chapter 40 Guam Food, Drug and Cosmetic Act (found on left side pocket of folder)
- C. Letter of National Association of Attorneys General to Hon. Margaret Hamburg, FDA Commissioner
- D. Letter of Association of State and Territorial Health Officials to Hon. Margaret Hamburg, FDA Commissioner
- E. Regulation of E-Cigarettes and Other Tobacco Products-Letter of FDA to Stakeholder
- F. FDA Consumer Health Information
- G. Electronic cigarettes and related Guam laws on tobacco
- H. Electronic Cigarettes as Tobacco Product FDA says





J.B. Van Hollen
Wisconsin Attorney General

PRESIDENT-ELECT Jim Hood Mississippi Attorney General

VICE PRESIDENT
Marty Jackley
South Dakota Attorney General

IMMEDIATE PAST PRESIDENT
Douglas Gansler
Maryland Attorney General

EXECUTIVE DIRECTOR

James McPherson

September 24, 2013

The Honorable Margaret Hamburg, Commissioner U.S. Food and Drug Administration 10903 New Hampshire Avenue Silver Spring, MD 20993

Re: FDA Regulation of E-Cigarettes

Dear Commissioner Hamburg,

The undersigned Attorneys General write to urge the Food and Drug Administration (FDA) to take all available measures to meet the FDA's stated deadline of October 31, 2013, to issue proposed regulations that will address the advertising, ingredients, and sale to minors of electronic cigarettes (also known as e-cigarettes).

State Attorneys General have long fought to protect their States' citizens, particularly youth, from the dangers of tobacco products. For example, every State Attorney General sued the major cigarette companies for the harm their products caused. With the protection of our States' citizens again in mind, the undersigned Attorneys General write to highlight the need for immediate regulatory oversight of e-cigarettes, an increasingly widespread, addictive product.

As you know, e-cigarettes are battery-operated products designed to deliver nicotine to the user by heating liquid nicotine, derived from tobacco plants, along with flavors and other chemicals, into a vapor that the user inhales. The nicotine found in e-cigarettes is highly addictive, has immediate bio-chemical effects on the brain and body at any dosage, and is toxic in high doses.<sup>1</sup>

E-Cigarette Sales are Growing Exponentially Using Marketing that Includes Television

Sales of e-cigarettes have grown rapidly in the United States, and after doubling every year since 2008, sales in 2013 are now accelerating even faster and projected to reach \$1.7 billion.<sup>2</sup> The cost of e-cigarettes has fallen

<sup>&</sup>lt;sup>1</sup> U.S. Surgeon General, U.S. Department of Health and Human Services, *The Health Consequences of Smoking: Nicotine Addiction* (1988); Emergency Response Safety and Health Database, National Institute for Occupational Safety and Health, Centers for Disease Control and Prevention, <a href="http://www.cdc.gov/niosh/ershdb/EmergencyResponseCard">http://www.cdc.gov/niosh/ershdb/EmergencyResponseCard</a> 29750028.html

<sup>&</sup>lt;sup>2</sup> Compare Josh Sanburn, Can Electronic Cigarettes Challenge Big Tobacco?, Time.com, Jan. 8, 2013, available at http://business.time.com/2013/01/08/can-electronic-cigarettes-challenge-big-tobacco/, (estimating 2013 sales at \$1 billion), with Stuart Elliot, E-Cigarette Makers' Ads Echo Tobacco's Heyday, New York Times, Aug. 29, 2013, available at http://www.nytimes.com/2013/08/30/business/media/e-cigarette-makers-ads-echo-tobaccos-heyday.html, (estimating 2013 sales at \$1.7 billion).

dramatically, as well, making them more affordable, and thus more attractive to young people. Unlike traditional tobacco products, there are no federal age restrictions that would prevent children from obtaining e-cigarettes, nor are there any advertising restrictions.

Along with the growth of e-cigarette sales, there has also been a growth of e-cigarette advertising over the past year. For example, in this year's Super Bowl broadcast, NJOY e-cigarettes purchased a 30-second television advertisement slot which reached at least 10 million viewers in certain markets and reportedly translated into a dramatic 30-40% increase in sales. The advertisement depicted an attractive man smoking an e-cigarette that looked just like a real cigarette. Since then, advertisements for e-cigarettes have regularly appeared on primetime television, making it easier for those advertisements to reach children. Moreover, e-cigarettes are not being marketed as smoking cessation devices, but rather as recreational alternatives to real cigarettes. Consumers are led to believe that e-cigarettes are a safe alternative to cigarettes, despite the fact that they are addictive, and there is no regulatory oversight ensuring the safety of the ingredients in e-cigarettes.

### E-Cigarettes Appeal to Youth

E-cigarettes contain fruit and candy flavors -- such as cherry, chocolate, gummy bear, and bubble gum -- that are appealing to youth. The FDA has banned such flavors from cigarettes and should take the same action regarding e-cigarettes. E-cigarettes and refills of the liquid nicotine solution used with e-cigarettes can easily be ordered online without age verification. By intentional use or mistaken ingestion from the non-child resistant containers, e-cigarettes and liquid nicotine refills can deliver dangerously high doses of liquid nicotine to youth.

In addition to flavors, e-cigarette manufacturers, such as eJuiceMonkeys.com and Magic Puff City E-cigarettes, use cartoon monkeys to sell e-cigarettes, even though for many years, the major manufacturers of traditional cigarettes have been banned from using cartoons to advertise. Finally, e-cigarette manufacturers, such as White Cloud Cigarettes, offer reusable e-cigarette "skins" -- known as Vapor Jackets -- that are intended to make the e-cigarette desirable or fashionable and are available in a variety of patterns that appeal to children, one of which uses images from the popular video game, Angry Birds. 5

Further, data from the 2011 and 2012 National Youth Tobacco Surveys (conducted by the Centers for Disease Control and Prevention) show that e-cigarette use among students doubled in the last year. Specifically, one in 10 high school students reported that they had tried an e-cigarette in the last year -- up from one in 20 in 2011, and 1.8 million middle and high school students said they had tried e-cigarettes in 2012. The increased usage among young people

<sup>&</sup>lt;sup>3</sup> Benjamin Wallace, *Smoke Without Fire*, New York Magazine, April 28, 2013, available at http://nymag.com/news/features/e-cigarettes-2013-5/.

<sup>&</sup>lt;sup>4</sup> See http://ejuicemonkeys.com/ and http://cityecigarettes.com/

<sup>&</sup>lt;sup>5</sup> See http://www.whitecloudelectroniccigarettes.com/accessories/vapor-jackets/

<sup>&</sup>lt;sup>6</sup> Catherine Corey, *Notes from the Field: Electronic Cigarette Use Among Middle and High School Students – United States*, 2011-2012, Centers for Disease Control and Prevention Morbidity and Mortality Weekly Report, September 6, 2013, available at

http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6235a6.htm?s\_cid=mm6235a6\_w

echoes the growth among adult users, and researchers indicated that aggressive marketing campaigns, in part, drove the increase.<sup>7</sup>

### The FDA has Authority to Regulate E-cigarettes and Protect the Public

In the Tobacco Control Act, Congress recognized that nicotine is an addictive drug, and virtually all new users of tobacco products are under the age of eighteen and are therefore too young to legally purchase such products. Congress further found that tobacco advertising and marketing contributes significantly to the teenage use of nicotine-containing tobacco products. To help prevent children from using tobacco products, the Tobacco Control Act imposed restrictions on advertising and marketing to youth. These restrictions should be applied to e-cigarettes, as well, to safeguard children from nicotine addiction and other potential health effects of e-cigarettes.

The FDA has authority to regulate electronic cigarettes as "tobacco products" under the Tobacco Control Act, as they are products "made or derived from tobacco" that are not a "drug," "device," or combination product. Case law, such as *Sottera, Inc. v. Food & Drug Administration*, 627 F.3d 891 (D.C. Cir. 2010), further supports the contention that e-cigarettes are "made or derived from tobacco" and can be regulated as "tobacco products" under the Tobacco Control Act.

We ask the FDA to move quickly to ensure that all tobacco products are tested and regulated to ensure that companies do not continue to sell or advertise to our nation's youth.

Very respectfully yours,

Martha Coakley

Massachusetts Attorney General

Michael Geraghty

Alaska Attorney General

Dustin McDaniel

Arkansas Attorney General

Mike DeWine Ohio Attorney General

Tom Horne

Arizona Attorney General

Kamala Harris

California Attorney General

<sup>&</sup>lt;sup>7</sup> Sabrina Tavernise, *Rise Is Seen in Students Who Use E-Cigarettes*, New York Times, September 5, 2013, available at http://www.nytimes.com/2013/09/06/health/e-cigarette-use-doubles-among-students-survey-shows.html

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October 22, 2013

The Honorable Margaret Hamburg, Commissioner U.S. Food and Drug Administration 10903 New Hampshire Avenue Silver Spring, MD 20993

Re: FDA Regulation of E-Cigarettes

Dear Commissioner Hamburg:

On behalf of the Association of State and Territorial Health Officials (ASTHO), we urge the Food and Drug Administration (FDA) to take all available measures to meet the FDA's stated deadline of October 31, 2013, to issue proposed regulations that will address the advertising, ingredients, and sale to minors of electronic cigarettes (known as e-cigarettes).

We believe that the FDA should have the authority to regulate the manufacturing, marketing, labeling, distribution, and sale of all tobacco products because it is the only agency with both the scientific expertise and regulatory authority to accomplish this mission. The FDA has the authority to regulate electronic cigarettes as "tobacco products" under the Tobacco Control Act, as they are products "made or derived from tobacco" that are not a "drug," "device," or combination product. Furthermore, case law, such as *Sottera, Inc. v. Food & Drug Administration*, 627 F.3d 891 (D.C. Cir. 2010), supports the contention that e-cigarettes are "made or derived from tobacco" and can be regulated as "tobacco products" under the Tobacco Control Act. We urge the FDA to act quickly to ensure that all tobacco products are tested and regulated.

Considerable controversy has arisen over the contents of e-cigarette cartridges. Evidence suggests that e-cigarettes contain lower levels of some common tobacco-related toxicants than traditional cigarettes, but an analysis by your agency identified concentrations of several impurities harmful to human health in e-cigarette cartridges. E-cigarettes are also produced by a number of different manufacturers, and the level of exposure to nicotine and toxins can vary widely between products, some of which contain nicotine levels that approach fatal doses. The amount of nicotine and other substances delivered in an e-cigarette often fluctuates between puffs taken by the same user. The labeling of e-cigarettes may also be misleading. Your agency also found that e-cigarettes claiming to be nicotine-free actually contain small amounts of nicotine. Research confirms that smoking e-cigarettes has many of the same immediate adverse effects on lung functions



as traditional cigarettes. As a relatively new and understudied product, however, any long-term health effects of e-cigarettes remain unknown.

E-cigarette users are most likely to be current smokers.<sup>8,9</sup> Research of tobacco consumers demonstrates that e-cigarettes may be used as a smoking cessation device or harm-reduction tool when substituted for cigarettes.<sup>10,11</sup> Your agency does not, however, formally recognize e-cigarettes as a form of nicotine replacement therapy.<sup>12</sup> Some tobacco experts have also cited concerns that instead of being used as a quit aid, e-cigarettes may be a gateway that entices more consumers—particularly youth—to initiate using tobacco products and become addicted to nicotine.<sup>13</sup>

High school students' use of e-cigarettes has doubled over the course of one year according to the data from the CDC's 2011 and 2012 National Youth Tobacco Surveys. In addition, 1.8 million middle and high school students said they had tried e-cigarettes in 2012. This increased use is likely facilitated by the availability of these products at an affordable price. Consumers overwhelmingly believe that e-cigarettes are effective for cessation and purchase these products despite the fact that e-cigarettes are not FDA-approved cessation devices. Furthermore, e-cigarette manufacturers are developing products and using marketing techniques--such as different flavors and visually appealing cartoons or ad placements--to entice youth into using e-cigarettes, demonstrating that cessation and individual harm reduction are not the manufacturers' goals. These trends only exaggerate the urgent need for quick action.

ASTHO's members, the chief health officials of the 57 state and territorial jurisdictions, are dedicated to formulating and influencing sound public health policy and ensuring excellence in state-based public health practice. Therefore, we urge that the FDA meet the October 31, 2013 deadline to issue regulations regarding e-cigarettes. We support the FDA's mission to reduce tobacco use and decrease the morbidity and mortality associated with tobacco consumption.

Because tobacco use is a major driver in causing chronic disease, ASTHO's members are concerned with its public health implications. Tobacco use is the single most preventable cause of disease, disability, and death in the United States. An estimated 443,000 people die prematurely each year from smoking or exposure to second-hand smoke, and another 8.6 million have a serious illness caused by tobacco use. <sup>16</sup> The emergence of novel tobacco products like e-cigarettes presents new challenges to state public health agencies and the public. Some key considerations for our membership include the inclusion of e-cigarettes into clean indoor air laws, youth marketing, and taxation laws. Until we understand more about the long-term health effects of e-cigarettes, these products should be tested and regulated as rigorously as conventional tobacco products.



Sincerely,

Paul E Jarus, no

Paul Jarris, MD, MBA Executive Director

Jewel Phila

Terry Cline, Ph.D. Terry Cline, PhD President

Oklahoma Commissioner of Health

Edward ! El

Jewel Mullen, MD, MPH, MPA Connecticut Commissioner ASTHO Prevention Policy Committee. Chair Ed Ehlinger, MD, MSPH Minnesota Commissioner of Health ASTHO Tobacco Issues Forum, Chair

Goniewicz ML, Knysak J, Benowitz N, et al. "Levels of selected carcinogens and toxicants in vapour from electronic cigarettes." *Tobacco Control*. March 6, 2013. Available at <a href="http://tobaccocontrol.bmj.com/content/early/2013/03/05/tobaccocontrol-2012-050859.abstract">http://tobaccocontrol.bmj.com/content/early/2013/03/05/tobaccocontrol-2012-050859.abstract</a>. Accessed 10-11-2013.

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<sup>&</sup>lt;sup>9</sup> Regan AK, Promoff G, Dube SR, Arrazola R. "Electronic nicotine delivery systems: adult use and awareness of the 'e-cigarette' in the USA." *Tobacco Control*. January 2013. 22(1):19-23. Available at <a href="http://tobaccocontrol.bmj.com/content/early/2011/10/27/tobaccocontrol-2011-050044.abstract">http://tobaccocontrol.bmj.com/content/early/2011/10/27/tobaccocontrol-2011-050044.abstract</a>. Accessed 10-11-2013.

<sup>&</sup>lt;sup>10</sup> Bullen C, Howe C, Walker N, *et al.* "Electronic cigarettes for smoking cessation: a randomised controlled trial." *Lancet.* Sept. 9, 2013. Available at <a href="http://www.thelancet.com/journals/lancet/article/PIIS0140-6736(13)61842-5/abstract">http://www.thelancet.com/journals/lancet/article/PIIS0140-6736(13)61842-5/abstract</a>. Accessed 10-11-2013.

<sup>&</sup>lt;sup>11</sup> Caponnetto P, Campagna D, Polosa R, *et al.* "EffiCiency and Safety of an eLectronic cigAreTte (ECLAT) as Tobacco Cigarettes Substitute: A Prospective 12-Month Randomized Control Design Study."



Plos ONE. June 2013, 8(6):1-12. Available at

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2013. 14 *Ibid*.

Health Physicians (AAHP) to the FDA, "Citizen Petition: Reclassify Nicotine Vaporizers (E-cigarettes) from 'Drug-Device Combination' to 'Tobacco Product'" (docket no. FDA-2010-P-0095 (Feb. 23, 2010), available at <a href="http://www.regulations.gov/#!docketDetail;D=FDA-2010-P-0095">http://www.regulations.gov/#!docketDetail;D=FDA-2010-P-0095</a>, accessed 10-11-2013). Examples of comments from the public on the petition include: (1) "Electronic cigarettes have helped me to quit smoking. I have been tobacco free for over 6 weeks now after being a smoker of over 20yrs"; (2) "E-cigarettes have help me quit smoking real cigarettes"; (3) "I was able to quit smoking using the vaping method and have not smoked in over 2 months." *Id.* Indeed, there are many websites on which e-cigarette users claim to have quit smoking by using e-cigarettes. For example, on PuffWeb.com's "How to Quit Smoking in 30 Days Using Electronic Cigarettes," the page author writes, "The following is an account of my (successful) attempt at quitting smoking using Electronic Cigarettes. I was able to become smoke free in 30 days" (available at <a href="http://www.puffweb.com/how-to-quit-smoking-in-90-days-using-electronic-cigarettes/">http://www.puffweb.com/how-to-quit-smoking-in-90-days-using-electronic-cigarettes/</a>, accessed 10-11-2013).

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Electronic cigarettes, or e-cigarettes, are essentially nicotine-delivery products, relatively new to the market with a growing following. It is a cylindrical device that mimics a real cigarette in its appearance and use. It consists of a battery, heating element, cartridges with or without nicotine, water and other ingredients. The levels of the nicotine can vary drastically and cartridges can also contain candy-like flavors. No smoke combustion is involved; the device emits a vapor when used. For this reason, e-cigarettes use is sometimes referred to as "vaping." E-cigarettes may contain ingredients that are known to be toxic to humans including carcinogens and diethylene glycol, a toxic chemical used in antifreeze. In initial lab tests, the Food and Drug Administration found detectable levels of carcinogens and toxic chemicals. Bystanders could be exposed to those chemicals if they inhale e-cigarette.

After a federal court ruled the Food and Drug Administration (FDA) does not have the authority to regulate e-cigarettes as drugs or drug delivery devices, in April 2011 the FDA announced that e-cigarettes can be regulated as a tobacco product under the Tobacco Control Act.

The Tobacco Control Act expressly allows state and local governments to regulate the sale and use of tobacco products, and authorizes them to enact measures that are more restrictive than federal law.

### **Guam Laws**

In reference to the above mentioned announcement of FDA, and studies that had been conducted which had been found to have detectable levels of carcinogens and toxic chemicals from vapors emitted by e-cigarettes are proven not safe for users and non-users to inhale. The following smoke-free laws in Guam can be applied to limit the public's exposure to secondhand e-cigarette vapor.

- 1. Public Law 28-80- Relative to the Regulation of Smoking Activities, known as the "Natasha Protection Act of 2005", the law which prohibits the use of any tobacco products inside the restaurant.
- 2. Public Law 30-80- Prohibits smoking within 20 feet of an entrance or exit of a public place where smoking is prohibited.
- 3. Public Law 31-102- Prohibits smoking in a motor vehicle when a child is present
- 4. Executive Order 2007-18- Mandates all government of Guam workplaces be tobacco-free.

There is a reasonable concern that the availability of e-cigarettes may lead to an increase in the incidence of young people smoking. The particular Guam law which can be applied is-Public Law 24-278, requires sellers of tobacco products to obtain a tobacco license and enforces the prohibition of sales of tobacco products to minors.

# FDA Warns of Health Risks Posed by E-Cigarettes

he Food and Drug Administration (FDA) has joined other health experts to warn consumers about potential health risks associated with electronic cigarettes.

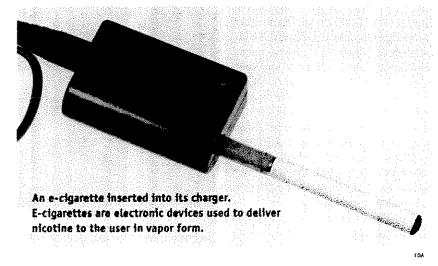
Also known as "e-cigarettes," electronic cigarettes are battery-operated devices designed to look like and to be used in the same manner as conventional cigarettes.

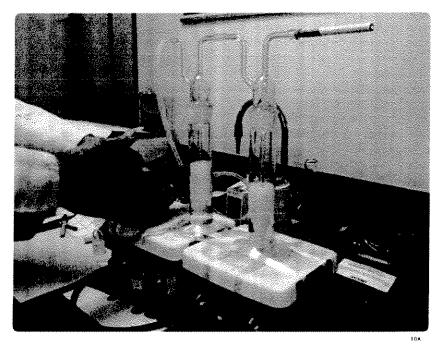
Sold online and in many shopping malls, the devices generally contain cartridges filled with nicotine, flavor, and other chemicals. They turn nicotine, which is highly addictive, and other chemicals into a vapor that is inhaled by the user.

"The FDA is concerned about the safety of these products and how they are marketed to the public," says Margaret A. Hamburg, M.D., commissioner of food and drugs.

The agency is concerned that

- e-cigarettes can increase nicotine addiction among young people and may lead kids to try other tobacco products, including conventional cigarettes, which are known to cause disease and lead to premature death
- the products may contain ingredients that are known to be toxic to humans
- because clinical studies about the safety and efficacy of these products for their intended use have not been





Air is drawn through an e-cigarette during a laboratory procedure that simulates a smoker taking a puff. The resulting vapor is tested.

submitted to FDA, consumers currently have no way of knowing

- whether e-cigarettes are safe for their intended use
- about what types or concentrations of potentially harmful chemicals, or what dose of nicotine they are inhaling when they use these products

The potential health risks posed by the use of e-cigarettes were addressed in a July 22, 2009, phone conference between Joshua M. Sharfstein, M.D., principal deputy commissioner of food and drugs; Jonathan Winickoff, M.D., chair of the American Academy of Pediatrics Tobacco Consortium; Jonathan Samet, M.D., director of the University of Southern California's Institute for Global Health; and Matthew T. McKenna, M.D., director of the Office on Smoking and Health at the national Centers for Disease Control and Prevention.

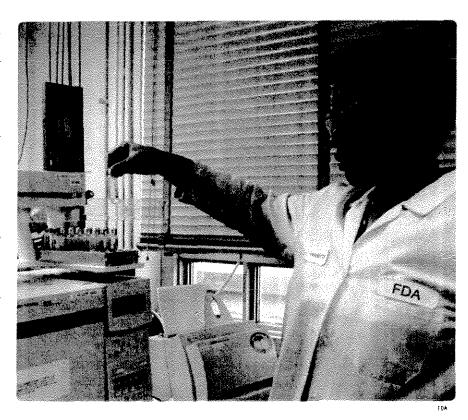
Conference participants stressed the importance of parents being aware of the health and marketing concerns associated with e-cigarettes. It was stated that parents may want to tell their children and teenagers that these products are not safe to use.

Of particular concern to parents is that e-cigarettes are sold without any legal age restrictions, and are available in different flavors (such as chocolate, strawberry and mint) which may appeal to young people.

In addition, the devices do not contain any health warnings comparable to FDA-approved nicotine replacement products or conventional cigarettes.

During the phone conference, which was shared with the news media, FDA announced findings from a laboratory analysis that indicates that electronic cigarettes expose users to harmful chemical ingredients.

FDA's Division of Pharmaceutical Analysis—part of the agency's Center for Drug Evaluation and Research—analyzed the ingredients in a small sample of cartridges from two leading brands of e-cigarette samples.



An FDA chemist uses a device set to the same temperature as an activated e-cigarette. This helps determine what might be inhaled by users of these products.

One sample was found to contain diethylene glycol, a toxic chemical used in antifreeze. Several other samples were found to contain carcinogens, including nitrosamines.

### **Agency Actions**

FDA has been examining and detaining shipments of e-cigarettes at the border and has found that the products it has examined thus far meet the definition of a combination drug device product under the Federal Food, Drug, and Cosmetic Act.

The agency has been challenged regarding its jurisdiction over certain e-cigarettes in a case currently pending in federal district court.

FDA is planning additional activities to address its concerns about electronic cigarettes.

Meanwhile, health care professionals and consumers may report seri-

ous adverse events or product quality problems with the use of e-cigarettes to FDA through the MedWatch program, either online at www.fda.gov/Safety/MedWatch/default.htm or by phone at 1-800-FDA-1088.

This article appears on FDA's Consumer Updates page (www.fda.gov/ForConsumers/ConsumerUpdates/default.htm), which features the latest on all FDA-regulated products.

### For More Information

FDA Press Release
www.fda.gov/NewsEvents/Newsroom/
PressAnnouncements/ucm173222.htm

E-Cigarettes: FDA Web page www.fda.gov/NewsEvents/ PublicHealthFocus/ucm172906.htm

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April 28, 2011

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# Electronic Cigarettes Regulated as Tobacco Products FDA Says

by Brian Malkin

Electronic Cigarrettes.bmp

On April 25, FDA announced to the public and sent out a letter to stakeholders that if would regulate electronic cigarettes as "tobacco products". FDA's announcement follows a decision, the letter states, that FDA will comply and not appeal a decision by the U.S. Court of Appeals for the D.C. Circuit, Sottera, Inc. v. FDA. In this decision, the Court held that FDA should regulate e-cigarettes as "tobacco products", not drug/devices, as FDA had attempted previously, unless the products are marketed with therapeutic claims, such as a smoking cessation product. The letter was signed by FDA Center Directors for the Center for Tobacco Products and the Center for Drug Evaluation and Research.

According to the letter, FDA will propose a regulation to extend the "tobacco product" definition

in the Family Smoking Prevention and Tobacco Control Act of 2009 ("Tobacco Control Act") that amended the Federal Food, Drug, and Cosmetic Act ("FD&C Act") to include not only e-cigarettes but other products "made or derived from tobacco". An exception to this classification would be for any product(s) that are "marketed for therapeutic purposes," where the product could be a drug, drug/device, or another type of FDA-regulated product. The Tobacco Act, however, prohibits tobacco products from being combined with other FDA-regulated products. FDA is taking this step, the letter explains, to ensure that "appropriate regulatory mechanisms" cover this extended class of products, which had previously been in limbo.

As part of the regulatory controls, all "tobacco products" must follow certain general controls, such as registration, product listing, ingredient listing, good manufacturing practice requirements, user fees for certain products and adulteration and misbranding provisions. In addition, as FDA's most recent draft guidance explains, "new tobacco product products" are any tobacco products marketed in the U.S. on February 15, 2007 or modified after February 15, 2007. "Modified-risk tobacco products" are products "sold or distributed for use to reduce harm or the risk of tobacco-related disease associated with commercially marketed tobacco products."

While e-cigarettes were first developed in 2003, many products only made their way into the U.S. market in more recent times, so it is likely that many e-cigarettes will require some form of premarket review or at least a finding of substantial equivalence. Time will tell whether this has been a victory or bane for the e-cigarette industry, but this appears to be a positive step for FDA to prevent certain

Antitrust (27)

Asia (10)

Biologics (133)

Biosimilars (71)

Canada (5)

Citizen Petitions (44)

Clinical Trials (44)

Cosmetics (3)

Dietary Supplements (15)

Enforcement (81)

European Drug Law (24)

European Union (41)

Exclusivity (13)

Financial Interest (3)

Foods (62)

GMPs (7)

Guidance (72)

Human Drugs (320)

Bioequivalence (16)

Generics (155)

Orphan Drugs (21)

Over-the-counter (14)

Pediatrics (6)

International Trade Commission

(3)

Key Officials (12)

Labeling (54)

Legislation (104)

Litigation (136)

Medical Countermeasures (4)

Medical Devices (82)

510(k) (13)

Meetings (104)

Organization (24)

Patent Term Extension (15)

Patents (91)

Radiation-Emitting Products (4)

Regulation (58)

Risk Management (30)

Science (24)

Tobacco Products (38)

Transparency (2)

Use Codes (14)

User Fees (24)

### EVENTS BLOGS ARTICLES

January 28, 2014
FLH's Brian Malkin to Speak at Ext. Pharma Summit on Risk Evaluation and Mitigation Strategies Summit in Alexandria, Virginia
On January 28, 2014, FLH. Partner Brian J. Malkin will speak on a panel \*Understand...

January 14, 2014
FLH's Brian Maikin Speaks at Q1
Productions Conference on
Maximizing Clinical Outcome
Assessments in Alexandria,
Virginia
On January 14, 2014, FLH
Partner Brian J, Maikin will speak
on "Understanding FDA's Draft...

December 11, 2013 FLH's Howard Rosenberg to tobacco-derived products from escaping regulatory oversight, along the lines suggested by several panel members at the Food and Drug Law Institute's Annual Conference earlier this month, as we reported here. For additional information about the *Sollera* case and FDA's previous attempts to regulate e-cigarettes as a drug/device, see our most recent blog here.

#### Categories:

- · Guidance,
- · Legislation,
- · Regulation,
- Tobacco Products

Posted by Frommer Lawrence & Haug | Permalink | Printable Version | Email This Post

Posted In: Guidance , Legislation , Regulation , Tobacco Products

considered "grandfathered" and are not subject to premarket review as "new tobacco products." A "tobacco product that is not "grandfathered" is considered a "new" tobacco product, and it is adulterated and misbranded under the FD&C Act, and therefore, subject to enforcement action, unless it has received premarket authorization or been found substantially equivalent. FDA has already developed draft guidance explaining flow manufacturers can request a determination from FDA that a "tobacco product" is "grandfathered."

We look forward to working with all stakeholders to ensure that the existing authorities granted the Agency are harnessed to best protect and promote the public health.

Sincerety.

Lawrence R. Deyton, M.S.P.H., M.D. Director Center for Tobacco Products

Janet Woodcock, M.D. Director Center for Drug Evaluation and Research

Page Last Updated: 04/25/2011

Note: If you need help accessing information in different file formats, see Instructions for Downloading Viewers and Players.



Home Food Drugs Medical Devices Radiation-Emitting Products Vaccines, Blood & Biologics Animal & Veterinary Cosmetics Tobacco Products

### News & Events

🐧 Hame 🐧 News & Events 🏺 Public Health Focus



SEARCH

Public Health Focus

### Regulation of E-Cigarettes and Other Tobacco Products

April 25, 2011

Dear Stakeholder:

The purpose of this letter is to provide stakeholders and the public with information, in light of a recent court decision, regarding the regulation of products made or derived from tobacco.

The Family Smoking Prevention and Tobacco Control Act of 2009 (Tobacco Control Act), which amends the Federal Food, Drug, and Cosmetic Act (FD&C Act), was enacted on June 22, 2009, and it provides the Food and Drug Administration (FDA) with authority to regulate "tobacco products." The FD&C Act, as amended by the Tobacco Control Act, defines the term "tobacco product," in part, as any product "made or derived from tobacco" that is not a "drug," "device," or combination product under the FD&C Act.

Under the FD&C Act, the definition of "drug" includes articles intended: (1) for use in the diagnosis, cure, mitigation, treatment or prevention of disease, or (2) to affect the structure or any function of the body. Similarly, "device" is defined to include articles intended: (1) for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, or (2) to affect the structure or any function of the body.

Between 2008 and 2010, the FDA determined that certain electronic cigarettes (e-cigarettes) were unapproved drug/device combination products and detained and/or refused admission to those offered for import by Sottera, Inc. and other manufacturers. Sotters, Inc. challenged that determination in court.

The U.S. Court of Appeals for the D.C. Circuit, in Sotters, Inc. v. Food & Drug Administration, 827 F.3d 891 (D.C. Cir. 2010), recently issued a decision with regard to e-cigarettes and other products "made or derived from tobacco" and the jurisdictional line that should be drawn between "tobacco products" and "drugs," "devices," and combination products, as those terms are defined in the FD&C Act. The court held that ecigarettes and other products made or derived from tobacco can be regulated as "tobacco products" under the Act and are not drugs/devices unless they are marketed for therapeutic purposes.

The government has decided not to seek further review of this decision, and FDA will comply with the jurisdictional lines established by Sottera.

Under the Tobacco Control Act, "tobacco products" are subject to a number of controls. Section 201(m)(4), for example, prohibits the marketing of a "tobacco product" in combination with any other article or product regulated under the FD&C Act (including a drug, biologic, food, cosmetic, medical device, or e dietary supplement). FDA has already issued a draft guidance that addresses the status of such products.

Moreover, Chapter IX of the FD&C Act subjects "tobecco products" to general controls, such as registration, product listing, ingradient listing, good manufacturing practice requirements, user fees for certain products, and adulteration and misbranding provisions. Chapter IX also subjects "new tobacco products" (i.e., products that are first marketed or modified after February 15, 2007), and "modified risk tobacco products" (i.e., products that are "sold or distributed for use to reduce harm or the risk of tobacco-related disease associated with commercially marketed tobacco products") to premarket review. Although the statute places certain "tobacco products" immediately under the general controls and premarket review requirements in Chapter IX (i.e., cigarettes; cigarette tobacco, roll-your-own tobacco, and smokeless tobacco). It also permits FDA, by regulation, to extend those controls to other categories of "tobacco products."

FDA plans to take the following steps to ensure that appropriate regulatory mechanisms govern all "tobacco products" and all other products made or derived from tobacco after the Sottera decision:

- The Agency Intends to propose a regulation that would extend the Agency's "tobacco product" authorities in Chapter IX of the FD&C Act, which currently only apply to certain specifically enumerated "tobacco products." to other categories of tobacco products that meet the statutory definition of "tobacco product" in Section 201(m) of the Act. The additional tobacco product categories would be subject to general controls, such as registration, product listing, ingradient listing, good manufacturing practice requirements, user fees for certain products, and the adulteration and misbranding provisions, as well as to the premarket review requirements for "new tobacco products" and "modified risk tobacco products."
- The Sottera decision states that products made or derived from tobacco, can be regulated under the Tobacco Control Act unless they are "marketed for therapeutic purposes," in which case they are regulated as drugs and/or devices. The Agency is considering whether to issue a guidance and/or a regulation on
- Section 201(rr)(4) of the Tobacco Control Act prohibits the marketing of "tobacco products" in combination with other FDA-regulated products. As mentioned, FDA has already issued a draft guidance on this provision, which it intends to finalize
- "Tobecco products" marketed as of February 15, 2007, which have not been modified since then are



## BUREAU OF BUDGET & MANAGEMENT RESEARCH

OFFICE OF THE GOVERNOR
Post Office Box 2950, Hagåtña Guam 96932

EDDIE BAZA CALVO GOVERNOR JOHN A. RIOS DIRECTOR

RAY TENORIO
LIEUTENANT GOVERNOR

FEB 20 2014

JOSE S. CALVO DEPUTY DIRECTOR

The Bureau requests that Bill No. <u>264-32 (COR)</u> be granted a waiver pursuant to Public Law 12-229 as amended for the following reason(s):

The proposed legislation adds *electronic cigarettes* as a prohibited tobacco product and possession thereof relative to minors.

The intent of the Bill is administrative in nature, as submitted for Legislative consideration.

ÍOHYA. R<del>ÍOS</del>

Director

# COMMITTEE ON RULES I Mina'trentai Dos na Liheslaturan Guåhan • The 32nd Guam Legislature

155 Hesler Place, Hagåtña, Guam 96910 • www.guamlegislature.com E-mail: roryforguam@gmail.com • Tel: (671)472-7679 • Fax: (671)472-3547

Senator Rory J. Respicio CHAIRPERSON MAJORITY LEADER

January 28, 2014

Senator Thomas C. Ada Vice Chairperson VIA E-MAIL

john.rios@bbmr.guam.gov

VICE CHAIRPERSON Assistant Majority Leader

Senator

Vicente (Ben) C. Pangelinan

Member

Speaker

Judith T.P. Won Pat, Ed.D.

Member

Senator

Dennis G. Rodriguez, Jr. Member

> Vice-Speaker Benjamin J.F. Cruz Member

Legislative Secretary Tina Rose Muña Barnes Member

Senator

Frank Blas Aguon, Jr. Member

Senator

Michael F.Q. San Nicolas

Member

Senator
V. Anthony Ada
Member
MINORITY LEADER

Senator Aline Yamashita Member John A. Rios Director Bureau of Budget & Management Research P.O. Box 2950 Hagåtña, Guam 96910

RE: Request for Fiscal Notes-Bill Nos. 264-32(COR) through 268-32(COR)

Hafa Adai Mr. Rios:

Transmitted herewith is a listing of *I Mina'trentai Dos na Liheslaturan Guåhan's* most recently introduced bills. Pursuant to 2 GCA §9103, I respectfully request the preparation of fiscal notes for the referenced bills.

Si Yu'os ma'åse' for your attention to this matter.

Very Truly Yours,

Senator Rory J. Respicio

Mary J. Respicio

Chairperson of the Committee on Rules

Attachment (1)

Cc: Clerk of the Legislature

Bill Nos.	Sponsors	Title
264-32 (COR)	Dennis G. Rodriguez, Jr. Brant T. McCreadie T.C. Ada R. J. Respicio T. R. Muña Barnes V. Anthony Ada Tommy. Morrison Chris M. Dueñas	AN ACT TO RELATIVE TO PROHIBITING THE SALE OR DISTRIBUTION OF ELECTRONIC CIGARETTES TO MINORS, BY ADDING A NEW § 6101(1) TO ARTICLE 1, AND AMENDING § 6400 OF ARTICLE 4, CHAPTER6, TITLE 11 GUAM CODE ANNOTATED.
265-32 (COR)	Vicente (ben) C. Pangelinan	AN ACT TO AUTHORIZE THE CHAMORRO LAND TRUST COMMISSION TO ENTER INTO ECONOMIC LEASES BY ADDING A NEW SECTION 75122, CHAPTER 75, TITLE 21 GUAM CODE ANNOTATED.
266-32 (COR)	Judith T. Won Pat, Ed.D. T.R. Muna Barnes Aline A. Yamashita, Ph.D.	AN ACT ADD A NEW §849.7 OF CHAPTER 8 OF TITLE I GUAM CODE ANNOTATED RELATIVE TO THE RENAMING OF THE TIYAN PARKWAY TO THE CHALAN MAG'HÅGA.
267-32 (COR)	Michael F.Q. San Nicolas T.C. Ada	AN ACT TO STRENGTHEN PROVISIONS FOR THE REPAIR OR DEMOLITION OF UNSAFE STRUCTURES IN GUAM'S BUILDING LAW, BY AMENDING§§ 66501, 66503, 66504, 66505, 66507 AND 66508 OF ARTICLE 5 AND § 66701 OF ARTICLE 7, EACH OF CHAPTER 66, TITLE 21, GUAM CODE ANNOTATED.
268-32 (COR)	Michael F.Q. San Nicolas	AN ACT TO APPROVE THE DEPARTMENT OF ADMINISTRATION'S IMPLEMENTATON PLANS OF THE 'GOVERNMENT OF GUAM COMPETITIVE WAGE ACT OF 2014', TO REQUIRE A PERFORMANCE-BASED STANDARD FOR DIRECTORS AND DEPUTY DIRECTORS OF LINE AGENCIES AND I MAGA'LÅHEN AND I SEGUNDU MAGA'LÅHEN.



I Mina'trentai Dos na Liheslaturan Guåhan • The 32nd Guam Legislature 155 Hesler Place, Hagåtña, Guam 96910 • www.guamlegislature.com E-mail: roryforguam@gmail.com • Tel: (671)472-7679 • Fax: (671)472-3547

Senator Rory J. Respicio Chairperson Majority Leader

January 17, 2014

Senator Thomas C. Ada VICE CHAIRPERSON ASSISTANT MAJORITY LEADER

Senator Vicente (Ben) C. Pangelinan Member

Speaker Judith T.P. Won Pat, Ed.D. Member

Senator Dennis G. Rodriguez, Jr. Member

> Vice-Speaker Benjamin J.F. Cruz Member

Legislative Secretary Tina Rose Muña Barnes Member

Senator Frank Blas Aguon, Jr. Member

Senator Michael F.Q. San Nicolas Member

Senator
V. Anthony Ada
Member
MINORITY LEADER

Senator Aline Yamashita Member

### **MEMORANDUM**

To: Rennae Meno

Clerk of the Legislature

Attorney Therese M. Terlaje Legislative Legal Counsel

From: Senator Rory J. Respicio

Chairperson of the Committee on Rules

Subject: Referral of Bill No. 264-32(COR)

As the Chairperson of the Committee on Rules, I am forwarding my referral of Bill No. 264-32(COR).

Please ensure that the subject bill is referred, in my name, to the respective committee, as shown on the attachment. I also request that the same be forwarded to all members of *I Mina'trentai Dos na Liheslaturan Guåhan*.

Should you have any questions, please feel free to contact our office at 472-7679.

Si Yu'os Ma'åse!

Attachment

### I Mina'Trentai Dos Na Liheslaturan Guahan Bill Log Sheet

BILL NO.	sponsor	TITLE	DATE INTRODUCED	DATE REFERRED	CMTE REFERRED	PUBLIC HEARING DATE	DATE COMMITTEE REPORT FILED	FISCAL NOTES
264-32 (COR)	Brant T. McCreadie T.C. Ada R. J. Respicio T. R. Muña Barnes	AN ACT TO RELATIVE TO PROHIBITING THE SALE OR DISTRIBUTION OF ELECTRONIC CIGARETTES TO MINORS, BY ADDING A NEW § 6101(I) TO ARTICLE 1, AND AMENDING § 6400 OF ARTICLE 4, CHAPTER 6, TITLE 11 GUAM CODE ANNOTATED.	10:03 a.m.	01/17/14	Committee on Aviation, Ground Transportation, Regulatory Concerns, and Future Generations			



Senator Michael San Nicolas «senatorsamocyas» agginudación s

### First Public Notice - March 12, 2014 Legislative Hearings

Senator Michael San Nicolas <senatorsannicolas@gmail.com>

Wed, Mar 5, 2014 at 9:32 AM

To: Senator Michael San Nicolas <senatorsannicolas@gmail.com> Bcc; aperez@gpagwa.com, Duane George <dmgeorge@guampdn.com>, Ed Davis <edavis@k57.com>, Frank Whitman <editor@mvguam.com>, Gerry Partido <gerry@mvguam.com>, gmmsinc@guam.net, Jason Salas <jason@kuam.com>, John Davis <john@kuam.com>, Kelly Cho <kcn.kelly@gmail.com>, Korean News <koreannews@guam.net>, KPRG <kprg@guam.net>, PDN Lifestyle fe@guampdn.com>, mabuhaynews@yahoo.com, Mindy Aguon <mindy@kuam.com>, Masako Watanabe <mwatanabe@guampdn.com>, K57 < news@k57.com>, Patti Arroyo < parroyo@k57.com>, radioprod@kuam.com, Ray Gibson <rgibson@k57.com>, Sabrina Salas Matanane <sabrina@kuam.com>, Steve Limtiaco <slimtiaco@guampdn.com>, sports@mvquam.com, tcoffman@k57.com, dcrisost@quam.gannett.com, weavert@pstripes.osd.mil, Pacific Daily News <news@guampdn.com>, Kevin Kerrigan <kevin@spbguam.com>, Bruce Hill <hill.bruce@abc.net.au>, Bruce Hill <pacificjournalist@gmail.com>, parroyo@spbquam.com, editor@saipantribune.com, Clynt Ridgell <clynt@spbguam.com>, mcpherson.kathryn@abc.net.au, communications@guam.gov, Troy Torres <troy.torres@guam.gov>, phnotice@guamlegislature.org, "jalerta1 ." <alerta.jermaine@gmail.com>, Matthew Baza <br/><baza.matthew@gmail.com>, Delisa Kloppenburg <delisakloppenburg@gmail.com>, Louella Losinio louella@mvguam.com>, david@mvguam.com, John Paul Manuel <jpmanuel@gmail.com>, josh@spbguam.com, Speaker Judi Won Pat <speaker@judiwonpat.com>, Vice Speaker Benjamin Cruz <senadotbjcruz@aol.com>, Senator Tina Muña Barnes <senator@tinamunabarnes.com>, Senator Rory Respicio <roryforguam@gmail.com>, "Dennis Rodriquez, Jr." <senatordrodriquez@qmail.com>, Senator Ben Pangelinan <senbenp@quam.net>, Senator Tom Ada <office@senatorada.org>, Senator Aline Yamashita <aline4families@gmail.com>, Senator Tony Ada <tony@tonyada.com>, Senator Chris Duenas <duenasenator@gmail.com>, Brant McCreadie <brantforguam@gmail.com>, Senator Brant McCreadie <senatorbrantmccreadie@gmail.com>, "Senator Frank Aguon, Jr." <aguon4guam@gmail.com>, Senator Mike Limtiaco <mike@mikelimtiaco.com>, Senator Tommy Morrison <tommy@senatormorrison.com>, mayormcdonald@hotmail.com, agatmayorsoffice@hotmail.com, asanmainamayorsoffice@yahoo.com, bmomayor@teleguam.net, bmovmayor@teleguam.net, Jessy Gogue <ocp.mayor@gmail.com>, MELISSA SAVARES <melissa.savares@gmail.com>, peter\_daigo@hotmail.com, hagatnamayor@hotmail.com, Doris Lujan <mayordorisfloreslujan@gmail.com>, nblas mangilaomayor@yahoo.com, vicemayor allan.unqacta@yahoo.com, mayorernestc@yahoo.com, mtm mayors office@yahoo.com, pitimayor@yahoo.com, Robert Hofmann <guammayor@gmail.com>, rudyiriarte@gmail.com, talofofomayor@gmail.com, "Mayor Louise C. Rivera" <mayorlcrivera.tatuha@gmail.com>, "Vice Mayor Ken C. Santos" <vicemayorksantos.tatuha@gmail.com>, Umatac Mayor <umatacmo@gmail.com>, kones.r@gmail.com, arleen81@gmail.com, kenjoeada@yahoo.com, anghet@hotmail.com, Ken Quintanilla <kenq@kuam.com>, raymond.qibson@quam.qov, Dale Alvarez <daleealvarez@gmail.com>, Responsible Guam <responsiblequam@gmail.com>, floterlaje@gmail.com, Regine Biscoe Lee <regineb.lee@gmail.com>, chuck.ada@guamairport.net, peterroy@guamairport.net, lorilee.crisostomo@bsp.guam.gov, doagridir@yahoo.com, carl.dominquez@dpw.quam.gov, eduardo.ordonez@clb.quam.gov, cqarcia@investquam.com, eric.palacios@epa.guam.gov, felixberto.dungca@grta.guam.gov, kpangelinan@visitguam.org, ndenight@visitguam.org, jbrown@portguam.com, monte.mafnas@dlm.guam.gov, david.camacho@galc.guam.gov, Michael Duenas <mjduenas@ghura.org>, fcamacho@ghura.org, martin.benavente@ghc.guam.gov, alfredo.antolin@dol.guam.gov. joseph.cameron@hrra.guam.gov, Cathy Gogue <cgogue@pbsguam.org>, adonis.mendiola@dya.guam.gov, jose.sanagustin@doc.guam.gov, pedro.leonguerrero@cqa.guam.gov, joey.sannicolas@gfd.quam.gov, fred.bordallo@gpd.guam.gov, chief@gpd.guam.gov, jim.mcdonald@ghs.guam.gov, benito.servino@disid.guam.gov, james.gillan@dphss.guam.gov, leo.casil@dphss.guam.gov, joseph.verga@gmha.org,

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### FIRST PUBLIC NOTICE

### FOR IMMEDIATE RELEASE

March 5, 2014

In accordance with the Open Government Law, relative to notice for public meetings, please be advised that the Committee on Aviation, Ground Transportation, Regulatory Concerns and Future Generations will be convening legislative hearings on **Wednesday**, **March 12**, **2014**, one hearing beginning at **9:30 a.m.** and another beginning at **2:00 p.m.** in *I Liheslaturan Guåhan*'s Public Hearing Room for the following items:

### 9:30 a.m. - Public Hearing

Bill No. 264-32 (COR), introduced by Senators Dennis G. Rodriguez, Jr., Brant T. McCreadie, Thomas C. Ada, Rory J. Respicio, Tina Muna-Barnes, V. Anthony Ada, Tommy Morrison, and Christopher M. Duenas: AN ACT RELATIVE TO PROHIBITING THE SALE OR DISTRIBUTION OF ELECTRONIC CIGARETTES TO MINORS, BY ADDING A NEW §6101(1) TO ARTICLE 1, AND AMENDING §6400 OF ARTICLE 4, CHAPTER 6, TITLE 11 GUAM CODE ANNOTATED.

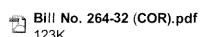
Nomination of **ROSALINDA A. TOLAN** to serve as a member of the A.B. Won Pat International Airport Authority, Guam Board of Directors

### 2:00 p.m. - Oversight Hearing

### Department of Revenue and Taxation

If written testimony is to be submitted for the hearings, copies should be delivered prior to the hearing date. Testimonies should be addressed to Senator Michael F.Q. San Nicolas and will be accepted via hand delivery to our office; our mailbox at the Main Legislature Building at 155 Hesler Place, Hagatna, Guam 96910; or via email to senatorsannicolas@gmail.com. In compliance with the Americans with Disabilities Act, individuals requiring special accommodations or services should contact the Office of Senator Michael F.Q. San Nicolas at 472-6453.

### 2 attachments



RTolan nomination.pdf 310K



Senator Michael San Nicolas Esenators innocuescaginari com-

### Second Public Notice - March 12, 2014 Legislative Hearings

Senator Michael San Nicolas <senatorsannicolas@gmail.com>

Mon. Mar 10, 2014 at 8:53 AM

To: Senator Michael San Nicolas <senatorsannicolas@gmail.com>

Bcc: aperez@gpagwa.com, Duane George <dmgeorge@guampdn.com>, Ed Davis <edavis@k57.com>, Frank
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<brantforguam@gmail.com>, Senator Brant McCreadie <senatorbrantmccreadie@gmail.com>, "Senator Frank

Aguon, Jr." <aguon4guam@gmail.com>, Senator Mike Limtiaco <mike@mikelimtiaco.com>, Senator Tommy Morrison <tommy@senatormorrison.com>, mayormcdonald@hotmail.com, agatmayorsoffice@hotmail.com,

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### SECOND PUBLIC NOTICE

### FOR IMMEDIATE RELEASE

March 10, 2014

In accordance with the Open Government Law, relative to notice for public meetings, please be advised that the Committee on Aviation, Ground Transportation, Regulatory Concerns and Future Generations will be convening legislative hearings on **Wednesday, March 12**, **2014**, one hearing beginning at **9:30 a.m.** and another beginning at **2:00 p.m.** in *I Liheslaturan Guåhan*'s Public Hearing Room for the following items:

### 9:30 a.m. - Public Hearing

Bill No. 264-32 (COR), introduced by Senators Dennis G. Rodriguez, Jr., Brant T. McCreadie, Thomas C. Ada, Rory J. Respicio, Tina Muna-Barnes, V. Anthony Ada, Tommy Morrison, and Christopher M. Duenas: AN ACT RELATIVE TO PROHIBITING THE SALE OR DISTRIBUTION OF ELECTRONIC CIGARETTES TO MINORS, BY ADDING A NEW §6101(1) TO ARTICLE 1, AND AMENDING §6400 OF ARTICLE 4, CHAPTER 6, TITLE 11 GUAM CODE ANNOTATED.

### 2:00 p.m. - Oversight Hearing

### Department of Revenue and Taxation

If written testimony is to be submitted for the hearings, copies should be delivered prior to the hearing date. Testimonies should be addressed to Senator Michael F.Q. San Nicolas and will be accepted via hand delivery to our office; our mailbox at the Main Legislature Building at 155 Hesler Place, Hagatna, Guam 96910; or via email to senatorsannicolas@gmail.com. In compliance with the Americans with Disabilities Act, individuals requiring special accommodations or services should contact the Office of Senator Michael F.Q. San Nicolas at 472-6453.

###



### Listserv: <a href="mailto:phnotice@guamlegislature.org">phnotice@guamlegislature.org</a> As of March 7, 2014

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### Senator Michael F.Q. San Nicolas

Chairman - Committee on Aviation, Ground Transportation, Regulatory Concerns and Future Generations 1 Mina trentai Dos Na Libeslahuran Gudhan | 32nd Guam Legislature



### PUBLIC HEARING

Wednesday, March 12, 2014 9:30 a.m. Public Hearing Room I Liheslaturan Guåhan

### **AGENDA**

- 1. Call to Order
- 11. Opening Remarks/Announcements
- III. Items for Public Consideration

Bill No. 264-32 (COR), introduced by Dennis G. Rodriguez, Brant T. McCreadie, Thomas C. Ada, Rory J. Respicio, Tina Muna Barnes, V. Anthony Ada, Tommy Morrison, and Christopher M. Duenas: "AN ACT RELATIVE TO PROHIBITING THE SALE OR DISTRIBUTION OF ELECTRONIC CIGARETTES TO MINORS, BY ADDING A NEW § 6101(1) TO ARTICLE 1, AND AMENDING § 6400 OF ARTICLE 4, CHAPTER 6, TITLE 11 GUAM CODE ANNOTATED."

- IV. Closing Remarks
- V. Adjournment

### **COMMITTEE ON RULES**

I Mina'trentai Dos na Liheslaturan Guåhan • The 32nd Guam Legislature 155 Hesler Place, Hagåtña, Guam 96910 • www.guamlegislature.com

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Senator Rory J. Respicio CHAIRPERSON MAJORITY LEADER

February 20, 2014

Memorandum

Senator Thomas C. Ada Vice Chairperson Assistant Majority Leader

To:

Rennae Meno

Clerk of the Legislature

Senator Vicente (Ben) C. Pangelinan Member

From:

Senator Rory J. Respicio

Majority Leader & Rules Chair

Speaker Judith T.P. Won Pat, Ed.D. Member

Subject:

Fiscal Note / Waiver

Senator

Dennis G. Rodriguez, Jr. Member

> Vice-Speaker Benjamin J.F. Cruz Member

Legislative Secretary Tina Rose Muña Barnes Member

Senator Frank Blas Aguon, Jr. Member

Senator Michael F.Q. San Nicolas Member

Senator
V. Anthony Ada
Member
MINORITY LEADER

Senator Aline Yamashita Member Hafa Adai!

Attached please find the waivers for the bill numbers listed below. Please note that the fiscal notes, or waivers, are issued on the bills as introduced.

### **FISCAL NOTE:**

Bill No. 256-32(COR)

### **WAIVER:**

Bill No. 264-32(COR)

Please forward the same to MIS for posting on our website. Please contact our office should you have any questions regarding this matter.

Si Yu'os ma'åse'!



671 4722825 10:16:19 a.m. 02-20-2014 2 /4



### BUREAU OF BUDGET & MANAGEMENT RESEARCH

OFFICE OF THE GOVERNOR
Post Office Box 2950, Hagåtña Guam 96932

EDDIE BAZA CALVO GOVERNOR JOHN A. RIOS DIRECTOR

RAY TENORIO LIEUTENANT GOVERNOR FEB 20 2014

JOSE S. CALVO DEPUTY DIRECTOR

Senator Rory J. Respicio
Chairperson, Committee on Rules
I Mina'trentai Dos na Liheslaturan Guåhan
The 31<sup>st</sup> Guam Legislature
155 Hesler Place
Hagåtna, Guam 96932

Hafa Adai Senator Respicio:

Transmitted herewith is Fiscal Note on the following Bill Nos.: <u>256-32(COR) and</u> Fiscal Note Waiver on the following Bill Nos.: <u>264-32(COR)</u>.

If you have any question(s), please do not hesitate to call the office at 475-9412/9106.

JOHN A. RIOS

Director

**Enclosures** 

cc: Senator Vicente (ben) Pangelinan



### BUREAU OF BUDGET & MANAGEMENT RESEARCH

OFFICE OF THE GOVERNOR
Post Office Box 2950, Hagåtña Guam 96932

EDDIE BAZA CALVO GOVERNOR JOHN A. RIOS DIRECTOR

RAY TENORIO LIEUTENANT GOVERNOR FEB 20 2014

JOSE S. CALVO DEPUTY DIRECTOR

The Bureau requests that Bill No. <u>264-32 (COR)</u> be granted a waiver pursuant to Public Law 12-229 as amended for the following reason(s):

The proposed legislation adds *electronic cigarettes* as a prohibited tobacco product and possession thereof relative to minors.

The intent of the Bill is administrative in nature, as submitted for Legislative consideration.

JOHN A. R<del>108</del>

Director

### **COMMITTEE ON RULES**



*I Mina'trentai Dos na Liheslaturan Guåhan* • The 32nd Guam Legislature 155 Hesler Place, Hagåtña, Guam 96910 • www.guamlegislature.com E-mail: roryforguam@gmail.com • Tel: (671)472-7679 • Fax: (671)472-3547

Senator Rory J. Respicio CHAIRPERSON MAIORITY LEADER

January 28, 2014

Senator Thomas C. Ada VICE CHAIRPERSON ASSISTANT MAJORITY LEADER

**VIA E-MAIL** 

john.rios@bbmr.guam.gov

Senator Vicente (Ben) C. Pangelinan Member John A. Rios
Director
Bureau of Budget & Management Research
P.O. Box 2950

Speaker Judith T.P. Won Pat, Ed.D. Member

Hagåtña, Guam 96910

Senator Dennis G. Rodriguez, Jr.

iguez, Jr. Member Hafa Adai Mr. Rios:

Vice-Speaker Benjamin J.F. Cruz Member Transmitted herewith is a listing of *I Mina'trentai Dos na Liheslaturan Guåhan's* most recently introduced bills. Pursuant to 2 GCA §9103, I respectfully request the preparation of fiscal notes for the referenced bills.

RE: Request for Fiscal Notes-Bill Nos. 264-32(COR) through 268-32(COR)

Legislative Secretary Tina Rose Muña Barnes Member Si Yu'os ma'åse' for your attention to this matter.

Senator

Frank Blas Aguon, Jr.

Member

Very Truly Yours,

Senator Michael F.Q. San Nicolas

n Nicolas Member My J. Respicio
Senator Rory J. Respicio

Chairperson of the Committee on Rules

Senator
V. Anthony Ada
Member
MINORITY LEADER

Attachment (1)

Senator Aline Yamashita Member

Cc: Clerk of the Legislature

Bill Nos. Sponsors		Title						
264-32 (COR)	Dennis G. Rodriguez, Jr. Brant T. McCreadie T.C. Ada R. J. Respicio T. R. Muña Barnes V. Anthony Ada Tommy. Morrison Chris M. Dueñas	AN ACT TO RELATIVE TO PROHIBITING THE SALE OR DISTRIBUTION OF ELECTRONIC CIGARETTES TO MINORS, BY ADDING A NEW § 6101(1) TO ARTICLE 1, AND AMENDING § 6400 OF ARTICLE 4, CHAPTER6, TITLE 11 GUAM CODE ANNOTATED.						
265-32 (COR)	Vicente (ben) C. Pangelinan	AN ACT TO AUTHORIZE THE CHAMORRO LAND TRUST COMMISSION TO ENTER INTO ECONOMIC LEASES BY ADDING A NEW SECTION 75122, CHAPTER 75, TITLE 21 GUAM CODE ANNOTATED.						
266-32 (COR)	Judith T. Won Pat, Ed.D. T.R. Muna Barnes Aline A. Yamashita, Ph.D.	AN ACT ADD A NEW \$849.7 OF CHAPTER 8 OF TITLE 1 GUAM CODE ANNOTATED RELATIVE TO THE RENAMING OF THE TIYAN PARKWAY TO THE CHALAN MAG'HÅGA.						
267-32 (COR)	Michael F.Q. San Nicolas T.C. Ada	AN ACT TO STRENGTHEN PROVISIONS FOR THE REPAIR OR DEMOLITION OF UNSAFE STRUCTURES IN GUAM'S BUILDING LAW, BY AMENDING§§ 66501, 66503, 66504, 66505, 66507 AND 66508 OF ARTICLE 5 AND § 66701 OF ARTICLE 7, EACH OF CHAPTER 66, TITLE 21, GUAM CODE ANNOTATED.						
268-32 (COR)	Michael F.Q. San Nicolas	AN ACT TO APPROVE THE DEPARTMENT OF ADMINISTRATION'S IMPLEMENTATON PLANS OF THE 'GOVERNMENT OF GUAM COMPETITIVE WAGE ACT OF 2014', TO REQUIRE A PERFORMANCE-BASED STANDARD FOR DIRECTORS AND DEPUTY DIRECTORS OF LINE AGENCIES AND I MAGA'LÅHEN AND I SEGUNDU MAGA'LÅHEN.						

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Senator Rory J. Respicio CHAIRPERSON MAIORITY LEADER

January 17, 2014

Senator Thomas C. Ada VICE CHAIRPERSON ASSISTANT MAJORITY LEADER

Senator Vicente (Ben) C. Pangelinan

Member

Speaker Judith T.P. Won Pat, Ed.D.

Member

Senator

Dennis G. Rodriguez, Jr. Member

> Vice-Speaker Benjamin J.F. Cruz Member

Legislative Secretary Tina Rose Muña Barnes Member

Senator Frank Blas Aguon, Jr. Member

Senator Michael F.Q. San Nicolas Member

Senator
V. Anthony Ada
Member
MINORITY LEADER

Senator Aline Yamashita Member **MEMORANDUM** 

To: Rennae Meno

Clerk of the Legislature

Attorney Therese M. Terlaje

Legislative Legal Counsel

From: Senator Rory J. Respicio

Chairperson of the Committee on Rules

Subject: Referral of Bill No. 264-32(COR)

As the Chairperson of the Committee on Rules, I am forwarding my referral of **Bill No. 264-32(COR).** 

Please ensure that the subject bill is referred, in my name, to the respective committee, as shown on the attachment. I also request that the same be forwarded to all members of *I Mina'trentai Dos na Liheslaturan Guåhan*.

Should you have any questions, please feel free to contact our office at 472-7679.

Si Yu'os Ma'åse!

Attachment

# 

### I MINA'TRENTAI DOS NA LIHESLATURAN GUÅHAN 2014 (SECOND) Regular Session

BILL No. <u>264</u>-32(COR)

Introduced by:

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DENNIS G. RODRIGUEZ, Jr. 9
BRANT T. MCCREADIE
THOMAS C. ADA
RORY J. RESPICION
TINA MUNA BARNES
V. ANTHONY ADA
TOMMY MORRISON
CHRISTOPHER M. DUENAS

AN ACT TO RELATIVE TO PROHIBITING THE SALE OR DISTRIBUTION OF ELECTRONIC CIGARETTES TO MINORS, BY ADDING A NEW § 6101(I) TO ARTICLE 1, AND AMENDING § 6400 OF ARTICLE 4, CHAPTER 6, TITLE 11 GUAM CODE ANNOTATED.

### BE IT ENACTED BY THE PEOPLE OF GUAM:

Section 1. Legislative Findings and Intent. *I Liheslaturan Guåhan* finds that the increasing popularity and unregulated distribution of electronic cigarettes is resulting in its widespread utilization by the youth in our island community.

I Liheslaturan Guåhan finds that it has been clearly been scientifically determined that nicotine is a harmful and highly addictive drug, the use of which may lead to illness or premature death. It further finds that the prevalent belief that e-cigarettes are simply safe smoke cessation devices is not applicable when considered within the context of its use by a minor. Although the matter of regulation has not yet been determined by the U.S. FDA, its utilization by minors is a reverse application of a product which leads to addiction, not the cessation of tobacco product utilization. The current usage of e-cigarettes has been reported to be highly prevalent amongst Guam's middle and high school students.

A number of states, principally California, Colorado, and Maryland, have succeeded in passing legislation banning the sale of electronic cigarettes to minors. Likewise, the states of Hawaii, Iowa, and New York have pending legislation under consideration with the similar intent of banning the sale or distribution of these products to minors.

I Liheslaturan Guåhan finds that electronic cigarettes contain nicotine, which is highly addictive substance, as is similarly found in tobacco products. For the purposes of this Act, I Liheslaturan Guåhan duly notes that according to the U.S. Food and Drug Administration, "Electronic cigarettes", also known as "E-Cigarettes", are battery operated products designed to deliver nicotine, flavor and other chemicals. They turn nicotine, which is highly addictive, and other chemicals into a vapor that is inhaled by the user.

It is the intent of *I Liheslaturan Guåhan* to include, regulate and prohibit under 11 GCA Ch 6 the sale or distribution of electronic cigarettes to a minor, or possession by a minor. It is, further, the intent of *I Liheslaturan Guåhan* that prohibition pursuant to this Section *solely* pertains to minors, and *shall* not prohibit the use or possession of an electronic cigarette by a person eighteen (18) years of age or older.

It is the intent of *I Liheslaturan Guåhan* to protect Guam's youth from nicotine addiction, as well as the potentially harmful effects of chemicals present in unregulated e-cigarette devices, by prohibiting the sale or distribution of electronic cigarettes to, or use by minors. It is, further, the *intent* to accomplish this objective by regulating electronic cigarettes along with tobacco products for the purposes of the enforcement of this prohibition, which *shall* apply *solely* to minors.

1	Section 2.	A new	subsection	(l) is	hereby	added	to §	6101	of Artic	cle	1,
2	Chapter 6, Title 11	l, Guam	Code Anno	tated,	to read:						

- "(1) Electronic cigarette, also known as "E-Cigarettes", are battery

  operated products designed to deliver nicotine, flavor and other chemicals. They

  turn nicotine, which is highly addictive, and other chemicals into a vapor that is

  inhaled by the user.
- (i) For the purposes of this Chapter and the prohibition pertaining

  solely to a minor pursuant to § 6400, tobacco product shall also be

  deemed to include and shall be similarly applicable to an electronic

  cigarette."
- Section 3. § 6400 of Article 4 of Chapter 6, Title 11, Guam Code Annotated, is hereby *amended*, to read:
- "§ 6400. Sale or Distribution of Tobacco Products and Electronic
   Cigarettes to Minors Prohibited.

It shall be a violation of this Chapter for any person to sell or distribute tobacco products or electronic cigarettes to minors. It shall not be a violation of this Chapter for any person to refuse to sell or distribute tobacco products or electronic cigarettes to any person whom the seller or the distributor reasonably believes to be under twenty-seven (27) years of age, and who is unable to produce acceptable photographic identification and proof that he is over the age of eighteen (18) years.

The sale or distribution of electronic cigarettes to minors, or its possession by a minor, is prohibited and *shall* be regulated and enforced pursuant to this Chapter. Any provision of this Chapter applicable to the regulation and prohibition

of the sale or distribution of a tobacco product to a minor, or possession by a minor, shall be applicable to electronic cigarettes and shall be regulated and enforced in the same manner as a tobacco product, to include the applicability of all penalties and fines.

- (a) Vending machines selling tobacco products <u>or electronic cigarettes</u> shall be located so that they are accessible only to persons over the age of eighteen (18) or are under the constant, direct supervision and unobstructed line-of sight of the person authorizing the installation or placement of the tobacco <u>or electronic cigarette</u> vending machine upon the premises he manages or otherwise controls, or his agent or employee. Said supervising adult shall ensure that minors do not purchase tobacco products <u>or electronic cigarettes</u> from vending machines. A person who authorizes the installation or placement of the tobacco <u>or electronic cigarette</u> vending machine upon premises he manages, or otherwise controls, and who knows or should know that the tobacco <u>or electronic cigarette</u> vending machine will likely be used by minors, shall be liable if minors purchase tobacco products <u>or electronic cigarettes</u> from said machines.
- (b) A licensee or an employer may distribute tobacco products or electronic cigarettes to any employee who handles tobacco products or electronic products in the course of the commercial distribution or sale of the products. In any proceeding, for the suspension or revocation of any license, and based upon a violation of this Section, proof that the defendant licensee or his agent or employee demanded and was shown, before furnishing any tobacco product or electronic cigarette to a minor, an identification card, shall be a defense to the charges.\*

- Section 4: Severability. *If* any provision of this law or its application to any person or circumstance is found to be invalid or contrary to law, such invalidity *shall not* affect other provisions or applications of this law which can be given effect without the invalid provisions or application, and to this end the provisions of this law are severable.
- Section 5: Effective Date. This Act *shall* be immediately effective upon enactment.