Delegate Mireku-North Testimony in Support of HB10 Uploaded by: Bernice Mireku-North

Position: FAV

BERNICE MIREKU-NORTH, ESQ. Legislative District 14 Montgomery County

Ways and Means Committee

Subcommitees

Early Childhood

Local Revenues



The Maryland House of Delegates 6 Bladen Street, Room 222 Annapolis, Maryland 21401 410-841-3539 · 301-858-3539 800-492-7122 *Ext.* 3539 Bernice.Mireku-North@house.state.md.us

THE MARYLAND HOUSE OF DELEGATES Annapolis, Maryland 21401

Testimony in Support of House Bill 1033: Business Regulation - Electronic Smoking Devices Manufacturers - Certifications February 20, 2024

Chair Wilson, Vice Chair Crosby, and esteemed members of the Economic Matters Committee, it is my pleasure to come before you and offer testimony in favor of **House Bill 1033: Business Regulation-Electronic Smoking Devices Manufacturers- Certifications**. This bill creates an important tool in stopping the influx of illegal Electronic Smoking Devices (ESDs), restricting access to illegal ESDs from minors, and potentially curbing the growing trend of youth vaping and its associated health risks.

Since Maryland's ESD laws were first passed in 2017, thousands of ESDs have flooded our communities. Currently in the marketplace, there are untold numbers of unregulated ESD products, including dangerous disposables, candy and fruit flavors attractive to children, and products designed to avoid detection in schools. These unregulated ESDs have fueled the growing problem of underage vaping in Maryland.

The solutions proposed by the Office of the Attorney General, through this bill, would create a regulatory and financial framework for the development and marketing of ESDs, enhancing transparency and enforcement, while holding manufacturers accountable for public safety.

House Bill 1033 will:

- Require that all ESDs have FDA authorization and that manufacturers apply to the State for approval *before* their products can be sold legally;
- Require manufacturers to identify each product to be sold, including their potency and whether they contain flavors that might appeal to children;
- Authorize the Attorney General to conduct investigations into ESD manufacturers and demand information to prove that the manufacturers are legitimate, law-abiding businesses that will take responsibility for the potential health risks that may be caused by their products;
- Require the Attorney General to publish a directory of legally certified ESDs, giving consumers and businesses clear guidance on which products are legal for sale. This would eliminate sales of ESDs manufactured by dubious companies that leave Maryland citizens holding the bag for the harms of their contraband product;
- Require signage for Vape Shop Vendors stating that tobacco sales may not be made to individuals under age 21; and
- Strengthen enforcement mechanisms on illegal ESDs by:
 - Making sales of ESDs that are not listed on the directory illegal and deemed contraband; and
 - Giving the Alcohol, Tobacco, and Cannabis Commission authority to inspect retailers and vape shops and to remove contraband products from stores – an enforcement method that has been extremely effective combating contraband cigarettes for over 20 years.

House Bill 1033 benefits local Maryland businesses *and* Maryland residents. The bill requires that all businesses selling ESDs obtain a specific ESD license. This bill is also seeking to change the current way of

selling ESD products by requiring ESDs to be sold only in face-to-face transactions at licensed Maryland retailers and vape shop vendors. Under current law, local businesses are disadvantaged as manufacturers can sell unregulated ESD products directly to Maryland consumers over the internet, completely bypassing local businesses. By requiring that ESDs be sold through responsible local businesses, **House Bill 1033** benefits Maryland retailers and vape shops, by allowing legally certified products in the market, while protecting the public health of its citizens.

House Bill 1033 also seeks to decrease the amount of illegal ESDs used by youth. Vaping is a long-standing issue for middle and high school students in my district, and I have heard countless complaints from constituents with children. Unregulated ESDs pose a particularly dangerous threat to the health of our youth. Stanford Medicine noted that one BC5000 unit (previously ELF Bar) had the nicotine content of over 590 cigarettes (or about 30 packs of regular cigarettes). ESDs are second only to cigarettes in overall use by adults, but for kids, ESDs are number one: more kids are using ESDs than cigarettes. Even though Maryland law bans the sale of ESDs to anyone under the age of 21, the most recent data from the Maryland Department of Health shows that 41.7% of high school seniors reported using an electronic vapor product and that 5% of high school seniors use them every day. Furthermore, nicotine is highly addictive and can harm developing brains. Early nicotine exposure can lay the groundwork for addiction to other drugs, and most adults who smoke began when they were underage.

Families, schools, and communities can only do so much to curtail the use – confiscating from backpacks, locking entrances to bathrooms to stop their students from vaping. These methods, however, do nothing to address the root of the problem: having these bad products in our stores in the first place. This bill addresses that and brings us one step closer to tackling the vaping epidemic for our youth.

Alabama, Louisiana, Oklahoma, and the city of San Francisco have also enacted ESD directories, while 15 other states have pending legislation. This bill, however, creates a stronger regulatory framework than these other states, ensuring that Maryland is leading the way in protecting the health and safety of Maryland's youth and communities. As such, I respectfully request a favorable report on **House Bill 1033**.

Bernise Mirchen North

HB 1033 - ECM - MHD - LOS.pdf Uploaded by: Laura Herrera Scott

Position: FAV



Wes Moore, Governor · Aruna Miller, Lt. Governor · Laura Herrera Scott, M.D., M.P.H., Secretary

February 20, 2024

The Honorable C. T. Wilson Chair, House Economic Matters Committee Room 231, House Office Building Annapolis, MD 21401-1991

RE: House Bill 1033 – Business Regulation - Electronic Smoking Devices Manufacturers -Certifications – Letter of Support

Dear Chair Wilson and Committee members:

The Maryland Department of Health (the Department) respectfully submits this letter of support for House Bill (HB) 1033 – Business Regulation - Electronic Smoking Devices Manufacturers -Certifications. HB 1033 establishes new licenses and fees for electronic smoking device (ESD) manufacturers, wholesalers, and retailers in Maryland; it also authorizes the Executive Director of the Alcohol, Tobacco, and Cannabis Commission (ATCC) to conduct unannounced inspections of licensed vape shop vendors. Finally, HB 1033 requires the Attorney General to create and maintain a common registry of ESD products that can be legally sold in Maryland.

HB 1033 updates the licensing regulatory scheme for ESDs in Maryland and better aligns Maryland law with best practices in tobacco prevention and control. Under current law, cigarette and other tobacco product (OTP) manufacturers, wholesalers, and retailers are not required to obtain a separate license to make, distribute, or sell ESDs in Maryland. Creating separate licenses for ESD manufacturers, wholesalers, and retailers; increasing licensure fees; and prohibiting online or direct-to-consumer sales of ESDs align with recommendations from the 2020 Comptroller's e-Facts Task Force on ESDs as ways to limit youth access.¹ HB 1033 creates a standard licensing system for all tobacco products (i.e., cigarettes, OTP, and ESDs) in Maryland; this is a benefit for the Department to know which retailer establishments are selling ESD products, particularly when conducting retailer inspections.

HB 1033 also requires the Attorney General to maintain a public directory of ESD products and accessories authorized to be sold in Maryland, and that all ESDs must receive a marketing authorization from the Food and Drug Administration (FDA) before ESD companies can register their devices for sale in the State. To date, the FDA has authorized 23 ESD products for sale in the United States.² Similar registries exist for cigarettes and OTP in Maryland.

¹ <u>https://www.marylandtaxes.gov/forms/etaskforce/final-e-facts-report02172020.pdf</u>

²https://www.fda.gov/tobacco-products/premarket-tobacco-product-applications/premarket-tobacco-product-marketing-granted-orders

²⁰¹ W. Preston Street · Baltimore, MD 21201 · health.maryland.gov · Toll Free: 1-877-463-3464 · Deaf and Hard of Hearing Use Relay

If you would like to discuss this further, please do not hesitate to contact Sarah Case-Herron, Director of Governmental Affairs at <u>sarah.case-herron@maryland.gov</u>.

Sincerely,

Laura Herrera Scott, M.D., M.P.H. Secretary

2024-02-16_OAG FWA testimony for HB1033 (EMC).pdf Uploaded by: Anna MacCormack

Position: FWA



CANDACE MCLAREN LANHAM *Chief of Staff*

CAROLYN A. QUATTROCKI Deputy Attorney General

STATE OF MARYLAND OFFICE OF THE ATTORNEY GENERAL

EMAIL amaccormack@oag.state.md.us WRITER'S DIRECT DIAL NO. (410) 576-7052

February 16, 2023

TO:	The Honorable C.T. Wilson Chair, Economic Matters Committee
FROM:	Anna MacCormack Assistant Attorney General, Office of the Attorney General
RE:	House Bill 1033 – Business Regulation – Electronic Smoking Devices Manufacturers – Certifications

The Office of Attorney General urges this Committee to report favorably on House Bill 1033 – Business Regulation – Electronic Smoking Devices Manufactures – Certifications.

House Bill 1033 brings much-needed improvements to Maryland's electronic smoking devices ("ESDs") law, Business Regulation Title 16.7. There have been many changes since Title 16.7 was enacted in 2017, including significant growth in the market and a changed federal landscape. House Bill 1033 incorporates improvements recommended by the Comptroller's 2020 Task Force on Electronic Smoking Devices to Maryland's ESD market and strengthens the licensing and regulatory systems for ESDs in the State.

ESD use has grown, including youth ESD use, and products have flooded the market. From January 2020 to December 2022, total U.S. e-cigarette unit sales increased by 46.6%, from 15.5 million to 22.7 million units.¹ ESDs are the second largest nicotine product category after traditional combustible cigarettes for adult users, but for youth, ESD use is higher than cigarettes: the 2021 Maryland High School Survey reports that while 3.6% of high school students smoked

¹ CDC, F.R. Ali et al. "E-cigarette Unit Sales by Product and Flavor Type, and Top-Selling Brands, United States, 2020–2022," *Morbidity & Mortality Weekly Report*, vol. 72 no. 25, 672–77 (June 23, 2023), https://www.cdc.gov/mmwr/volumes/72/wr/pdfs/mm7225a1-H.pdf.

This bill letter is a statement of the Office of Attorney General's policy position on the referenced pending legislation. For a legal or constitutional analysis of the bill, Members of the House and Senate should consult with the Counsel to the General Assembly, Sandy Brantley. She can be reached at 410-946-5600 or sbrantley@oag.state.md.us.

cigarettes, 14.7% of high school students currently used ESDs—the equivalent of more than 4 students in a class of 30.² A 2022 national survey of students found that of the 2.55 million U.S. middle and high school students currently using e-cigarettes, most reported using flavored products, and, among those students, approximately 7 of 10 used fruit flavors.³ Nicotine is highly addictive and can harm developing brains. Early nicotine exposure can prime the brain for addiction to other drugs, and nearly 90% of adults who smoke daily started smoking by age 18, and 98% by age 25.

As sales and use have risen, changes have also come to the legal landscape. In 2016, pursuant to the Family Smoking Prevention and Tobacco Control Act, 21 U.S.C. § 387 *et seq*. ("Tobacco Control Act"), the FDA adopted the "Deeming Rule," which provided that ESDs would be treated as "tobacco products." This meant that ESDs were subject to the Tobacco Control Act and regulated by FDA. Products that were on the market as of August 8, 2016, could remain on the market provided the manufacturer submitted a premarket tobacco product application to the FDA by September 9, 2020. In other words, to legally market a new tobacco product—which includes ESDs—a company must apply for and receive a written marketing order from FDA.

The window for ESD manufacturers to apply for a marketing order has now closed and the FDA has taken action on most of the approximately 26 million premarket tobacco product applications it received. Millions of products either received denials or received refuse to accept or refuse to file letters from the FDA. For non-tobacco nicotine products, the FDA reviewed more than 9,000 applications but has not issued any marketing orders for these. An unknown number of ESDs still have pending premarket applications, and the FDA has now issued marketing orders for 23 tobacco-flavored e-cigarette and vapor products. This process has finally given such much-needed clarity regarding what ESDs are authorized for sale by federal law.

House Bill 1033 would improve Maryland's ESD industry in two main ways. First, House Bill 1033 would bring the ESDs sold in Maryland into compliance with federal and state law. It does this by establishing an ESD directory, similar to the cigarette directory that Maryland has had for twenty years. To comply with federal and existing state law, House Bill 1033's directory would only include ESDs that are legal for sale because they have received FDA marketing orders. This would protect Maryland teens and other consumers from ESDs made by unknown manufacturers with unregulated and potentially dangerous product components. In addition, by establishing a directory of legal products, House Bill 1033 will enable law-abiding State licensees to avoid selling illegal and dangerous products unknowingly. House Bill 1033 empowers the Office of the Attorney General, which would administer the ESD directory, as it does for the existing cigarette

² Maryland Dep't of Health, *Youth Risk Behavior Survey/Youth Tobacco Survey (YRBS/YTS) 2021-2022*, <u>https://health.maryland.gov/phpa/ccdpc/Reports/Pages/State-Level-Data,-2021-2022.aspx</u>.

³ CDC, M. Cooper et al., "Notes from the Field: E-cigarette Use Among Middle and High School Students—United States, 2022," *Morbidity & Mortality Weekly Report*, vol. 71 no. 40, 1283–85 (Oct. 7, 2022), https://www.cdc.gov/mmwr/volumes/71/wr/pdfs/mm7140a3-H.pdf.

directory, to obtain information about the companies and their products before allowing ESDs to enter Maryland. Furthermore, applicants to the directory must either register to do business in the State or appoint an agent for service of process, enabling the State to find these manufacturers if there are any violations of the law.

An ESD directory is a commonsense solution to a market that has been flooded with noncompliant products, including disposable products and synthetic nicotine products. The Associated Press reports that according to sales data, since 2020 the number of different ESDs sold in the United States has tripled to more than 9,000, "driven almost entirely by a wave of unauthorized disposable vapes from China."⁴ With so many products entering and exiting the market, it is difficult for wholesalers, retailers, and vape shop vendors to know what ESDs are legal for sale, resulting in many illicit products remaining available to consumers.

Additionally, House Bill 1033 grants the Alcohol, Tobacco, and Cannabis Commission ("ATCC") authority to conduct unannounced inspections of retailers and vape shop vendors to ensure compliance with the Title and the requirement that ESDs may only be sold to individuals age 21 and older. The ATCC already conducts retail checks for cigarettes and Other Tobacco Products ("OTP"), including directory checks for those products. Giving the Commission similar authority to check ESD compliance is another way in which House Bill 1033 seeks to treat ESDs similarly to traditional tobacco products.

The second way in which House Bill 1033 improves Maryland's ESD industry is by making important modifications to Maryland's ESD licensure system. Right now, many entities selling ESDs do not have ESD licenses because they already have cigarette or OTP licenses, and the law exempts them from getting a separate ESD license. House Bill 1033 requires that all businesses obtain a separate ESD license, enabling the State to know what businesses are buying and selling ESDs in Maryland. House Bill 1033 also requires all sales be made by and to businesses with Maryland ESD licenses, as is required for traditional tobacco products.

House Bill 1033 would also close a significant loophole in the current law that allows ESD manufacturers to sell their products over the internet or by mail directly to consumers. Online sales are not allowed for cigarettes or OTP, and House Bill 1033 removes this exception for ESDs so that ESDs are treated the same as cigarettes and OTP. House Bill 1033 requires that all purchases by consumers be face-to-face sales, which are better able to prevent illegal, underage sales.

The provisions in House Bill 1033 come from the State's long experience with traditional tobacco products, as well as the recommendations of the Comptroller's Task Force on Electronic Smoking

⁴ M. Perrone, "Thousands of unauthorized vapes are pouring into the US despite the FDA crackdown on fruity flavors," *Associated Press* (June 26, 2023), <u>https://apnews.com/article/fda-vapes-vaping-elf-bar-juul-80b2680a874d89b8d651c5e909e39e8f</u>.

Devices.⁵ The Task Force, which was established in 2019, was made up of 40 appointed members from every region of the State, comprised of educators, ESD retailers, public health experts, concerned parents, and local and state elected officials. After holding four public meetings and soliciting feedback from both industry and the public, the Task Force's 2020 Report made two recommendations found in House Bill 1033: banning all direct-to-consumer internet and mail order sales of ESDs, and requiring separate ESD licenses with higher fees. The Report also recommended obtaining more information from manufacturers to better "know precisely what e-liquids and ESD devices contain before these products ever reach consumers." House Bill 1033 improves on that by requiring that ESDs sold in the State have marketing orders issued by the FDA.

Finally, the anticipated proposed amendments would make additional improvements to Maryland's ESD laws. These amendments would expand the ESDs permitted for sale by allowing both ESDs with marketing orders, but also those that have timely applied for FDA authorization and are awaiting a ruling or that have a court order staying a final decision on the directory. Only licensed vape shops would be permitted to sell the larger class of ESDs with pending applications, keeping them out of convenience stores and restricting them to stores that cater to individuals over the age of 21. The amendments would also establish a two-tiered fee system for Maryland's ESD directory: manufacturers applying for ESDs with marketing orders will have a fee of \$1,000 per product, while ESDs with pending FDA applications will have a fee of \$5,000 per product, paid to the Attorney General to be used for administration and enforcement of this law. Similarly, a new subsection is included requiring that manufacturers post security, the amount of which depends on what products they are certifying. These funds would be available to the ATCC for the costs of collection and disposing of any ESDs taken off the directory or which violate federal, state, or local law.

The amendments would also revise the penalties section, providing the State with tools to effectively enforce the Directory. Sales of off-directory products would also be deemed an unfair and deceptive trade practice in violation of the Consumer Protection Act. Lastly, the amendments would provide additional process when a product is removed from the directory.

For the foregoing reasons, the Office of the Attorney General urges a favorable report on House 1033.

cc: Committee Members

⁵ Comptroller's Task Force on Electronic Smoking Devices, *Electronic Smoking Devices in Maryland: A Safer Path Forward* (2020), <u>https://mdlaw.ptfs.com/awweb/pdfopener?md=1&did=31028</u>.

HB1033_FWA_MedChi, MDCSCO_Bus. Reg. - Electronic S

Uploaded by: Pam Kasemeyer Position: FWA



The Maryland State Medical Society

1211 Cathedral Street Baltimore, MD 21201-5516 410.539.0872 Fax: 410.547.0915

1.800.492.1056

www.medchi.org

- MARYLAND/DISTRICT OF COLUMBIA SOCIETY OF CLINICAL ONCOLOGY
- TO: The Honorable C.T. Wilson, Chair Members, House Economic Matters Committee The Honorable Bernice Mireku-North
- FROM: Pamela Metz Kasemeyer J. Steven Wise Danna L. Kauffman Andrew G. Vetter Christine K. Krone
- DATE: February 20, 2024
- RE: **SUPPORT WITH AMENDMENT** House Bill 1033 Business Regulation Electronic Smoking Devices Manufacturers Certifications

The Maryland State Medical Society (MedChi), and the Maryland/District of Columbia Society of Clinical Oncology (MDCSCO), **supports with amendment** House Bill 1033.

House Bill 1033 establishes the framework for licensure and regulation of electronic smoking device manufacturers whose products are sold in Maryland. It requires tobacco product manufacturers and electronic smoking device manufacturers to meet certification requirements and pay a certification fee. The revenues from the certification fee will be distributed to a special fund to be used by the Office of the Attorney General for enforcement of regulatory oversight.

MedChi and MDCSCO are supportive of bill and its provisions but would like to include an amendment that would allocate a portion of the certification fee revenues to be used for working with a non-profit organization that is recognized by the Accreditation Council for Continuing Medical Education to provide harm reduction public health education. By staying informed about the latest research and best practices in harm reduction, healthcare professionals can incorporate evidence-based interventions into their clinical practice and public health efforts. With the adoption of this amendment, MedChi and MDCSCO support House Bill 1033.

For more information call: 410-244-7000

Kleykamp HB2033 Testimony to Maryland.pdf Uploaded by: Bethea Kleykamp

Position: UNF

House Ecomonics Matters Committee HB1033: "Business Regulation - Electronic Smoking Devices Manufacturers – Certifications" Hearing February 20, 2024 at 1pm in the House

Dear Maryland Delegates Mireku-North, Rosenberg, and Miller:

My name is Annie Kleykamp (PhD, MA) writing as a scientist with over 20 years of experience studying the effects of nicotine and tobacco. I have also been a voter and taxpayer in Maryland for the last 16+ years. I am urging you to **reject HB 1033**, which would require the state to enforce regulations that could restrict access to safer products among people who smoke.

Tobacco smoking, the leading cause of death and disease in the world, continues to be the most commonly way people use tobacco in Maryland and the United States. Approximately 1,000 people die each day in America from its use. One of those people was my father who passed away at age 63 as a lifelong smoker who had not been able to quit despite having a medical degree and access to FDA-approved medications for cessation.

These FDA-approved medications have low success rates and people who smoke need more options for helping them quit.

E-cigarettes ("vaporized products") are a tool for reducing the harms of smoking. Since Ecigarettes were introduced to America in 2006 there has been growing evidence demonstrating their safety and reduced harm. Leaders in science and medicine (the Cochrane Collaboration and the <u>New England Journal of Medicine</u>) have now published data supporting the conclusion that vapor products/e-cigarettes result in <u>less exposure to harm chemicals</u> than smoking and can serve as a tool for <u>stopping smoking</u>. These reviews of the evidence included over 20,000 patients and demonstrated that e-cigarettes were more effective than existing smoking cessation medication such as nicotine replacement therapy.

People who smoke deserve as many options as possible to stop their use of combustible tobacco/smoking to prevent early death and suffering from conditions such as lung cancer and COPD.

If this legislation is enacted, thousands of people across Maryland will lose access to smoke-free products that are helping them live smoke-free lives. To be blunt, support for these bills is sacrificing the lives of people who smoke.

In Baltimore, where I live and work, and throughout the US, these lives are disproportionately older, non-White, and living below the poverty line. This means that smoking disproportionately harms people historically marginalized groups that need help stopping smoking in whatever way possible.

Unfortunately, combustible cigarettes remain easily accessible on most shelves of convenience stores and gas stations.

Meanwhile, the FDA is failing to regulate smoke-free nicotine products in a way that protects public health. The federal regulator's delay in decision-making and arbitrary denial orders are also bogging the agency down with lawsuits and reputational damage. Enforcing a de facto ban on products that FDA is supposed to be reviewing will come at the expense of Maryland taxpayers and public health.

Our goal in Maryland should be 1) reduce or stop use of combustible tobacco use. For some people this means switching to safer, non-smoking products and not necessarily completely stopping nicotine. People die from the tar of smoking, not the nicotine.

Please reject HB 1033 and thank you for listening to my comments.

Bethea A Kleykamp, PhD, MA Assistant Professor, University of Maryland School of Medicine <u>bkleykamp@som.umaryland.edu</u> 410-402-0252

HB 1033 Candice Gott Opposition.pdf Uploaded by: Candice Gott

Position: UNF

Candice Gott

Opposition to HB1033

Good evening, Chair and Committee. My name is Candice Gott, and I am a board member of the Maryland Vapor Alliance. Our group exists to promote fair regulation for vapor products, and to help protect small businesses.

This is a bill being lobbied by big tobacco in all states across America and for the most part, legislators have done an excellent job at seeing right past the same old tactics used by big tobacco and their lobbying teams.

This bill leaves twenty big tobacco products on the shelf and bans everything else. We are talking about the products from the corporations who created an issue with teen use, who marketed their products unethically. I have owned my business for 10 years and there was never any issues until big tobacco stepped in and sunk their claws into our industry.

If this bill passes as is, there will be no more open systems vapor products on the market. My customers using 3mg of nicotine will be forced to use products that are high in nicotine, 50mg+. That is, unless they decide to go back to smoking cigarettes, another great win for big tobacco, or get products on the black market. If they decide to get their products on the black market or another state, there will be no taxes collected for the state of Maryland. In fact, Maryland stands to lose ninety million dollars annually if this bill passes.

Next, small businesses vape shops and manufacturers sued the FDA for the shortcoming of the pre-market tobacco application (PMTA) process, and the FDA lost. First, the circuit court issued an injunction to the FDA to allow products to continue being sold, then the final decision was handed down a few weeks ago. This judge's decision included calling the FDA arbitrary and capricious towards small businesses in their handling of the Pre-market

tobacco applications, as well as saying the FDA sent these small businesses on a wild goose chase. Therefore, the circuit court shot down the PMTA process while Maryland is trying to make it the gold standard.

This bill is bad for business, and we are asking for an unfavorable report.

George Falter MD HB1033 Oppose V2.pdf Uploaded by: Christopher Warthen

Position: UNF

Chair Wilson, Vice-Chair Crosby, and esteemed members of the House Committee on Economic Matters,

My name is Brian Blevins, and I represent the George J. Falter Company, a full-line distribution company in Maryland. Our company, owned and operated by a fifth-generation family, has been in business since 1878. Among our many products, we sell vapor products, and I am here today to discuss the importance of establishing a vapor directory in Maryland.

Our company is committed to complying with FDA regulatory guidelines on vapor products, particularly regarding the Pre-Market Tobacco Application (PMTA) process. We ensure that the vapor products we sell have either received a marketing granted order or are pending a final decision on their PMTA from the FDA. Unfortunately, there continues to be a lack of clarity from the FDA on which vapor products can or cannot be legally sold. This has led to a very large number of retailers and some wholesalers unknowingly carrying illegal products, including hundreds of flavored disposable vapes from China. These are the products that our impacting our youth, and these are also the products that are circumventing the PMTA process.

A vapor directory is crucial to address this issue, but it needs to be established correctly. It should list products that have submitted a PMTA to the FDA by the required deadline in 2020 and are either approved OR are still under review by the FDA. We also urge the state to establish a specific deadline by which the directory should be first published as well as require regular monthly updates to the listing. This will ensure that retailers and wholesalers always have the most up-to-date information when a vapor product is either added or removed from the directory.

The George J Falter Company fully supports the establishment of a vapor directory in Maryland, but I do not believe that language of HB 1033 is expansive and clear enough. For that reason, I would like to direct your attention to HB 1197; this bill includes some additional details and specifics that are truly needed for a directory to be effective and successful from the onset.

Today, I urge this committee to vote against HB 1033. As an alternative, I am asking that you put your full support behind HB 1197 when that vapor directory bill comes before you in early March.

Thank you for your attention to this important issue.

Christopher Warthen

AVM Maryland HB 1033 Testimony PMTA Registry.pdf Uploaded by: Gregory Conley

Position: UNF



February 20, 2024

Chairman Wilson and members of the House Economic Matters Committee,

On behalf of the American Vapor Manufacturers (AVM), a trade group representing a broad spectrum of small business owners within the nicotine vaping industry, I am writing to urge you to reject HB 1033. At a time when sales of combustible cigarettes are plummeting in Maryland and across the United States, importing the Food & Drug Administration's prohibitionist vaping product regulations into the state would lead to negative consequences for small businesses and public health.

HB 1033 would do little to nothing to address youth vaping, as adolescents are accustomed to purchasing their adult products through illicit markets. What HB 1033 will do is shut down responsible small businesses and make it more difficult for Maryland's nearly 225,000 adult vapers to access the products they want to use.

Overview of House Bill 1033

HB 1033 proposes an effective prohibition on all vaping products introduced in the past eight years by establishing a Pre-Market Tobacco Application (PMTA) directory. Placement on the directory would be limited exclusively to manufacturers who submitted a PMTA for a product that was on the market on August 8, 2016, to the FDA by September 9, 2020, and are awaiting or have received authorization.

The corporate proponents of this bill deliberately chose the September 2020 date in a bid to sideline non-tobacco nicotine products, the manufacturers of which were not required to submit their PMTAs until mid-2022. Consequently, over 9,000 non-tobacco nicotine products under FDA review today will be ineligible for inclusion in the directory.

The end effect of HB 1033 will be to eliminate over 95% of nicotine vaping products available at Maryland specialty retailers. This will disproportionately benefit large, out-of-state tobacco companies by decimating their competition.

Implications for Small Businesses

Imagine attempting to operate a cell phone store, but being restricted to selling iPhone models introduced in the mid-2010s; this analogy mirrors the predicament nicotine vaping businesses would face under HB 1033.

The FDA has already denied over 99% of the 26 million PMTAs it received from vaping manufacturers. Two months ago, the agency informed a Maryland district court judge that it intended to complete review on the remaining 1% by June of 2024.

This bill threatens the viability of genuine Maryland enterprises and the jobs of their employees. Simply put, it will be impossible to both run a profitable business and comply with the law.

AMERICAN VAPOR MANUFACTURERS

Unfunded Enforcement Mandate

The proposed \$1,000 per manufacturer fee falls far short of what would be necessary to create even the *appearance* of enforcement. As it stands today, just three manufacturers have received PMTAs from the FDA for 23 products. All are from large tobacco companies and limited to tobacco flavors only.

Of the 23 products approved thus far, 3 products were so unpopular they've been discontinued. *Absent an extraordinary change in the FDA's review process, the fee structure proposed in HB* **1033** *may only generate* **\$3,000-\$5,000** *annually for enforcement of this law.* This is starkly inadequate compared to the State of Virginia's estimated annual enforcement cost of at least \$2.1 million for a PMTA directory.

Consequences for Public Health and Consumer Choice

There is a reason why Altria—America's largest cigarette company—is such a fervent advocate for PMTA registries. Last October, they blamed disposable vaping products for causing their cigarette sales to decline faster than anticipated. The news for Altria has only soured since. Just last week, the investment firm Barclay's predicted that unless disposable vaping products are quickly eliminated, Altria will have to reduce its predicted earnings for FY 2024.

Altria's advocacy suggests their interest in PMTA registries is not about 'fairness' in the market, or even to obtain a competitive advantage for their vaping product. *Rather, it appears Altria is banking on adult vapers returning to combustible cigarettes.*

No State Has Successfully Implemented a PMTA Directory

HB 1033's restrictive product directory could push consumers toward unregulated markets, heightening public health risks and fostering crime, including cartel involvement. Both adolescents and young adults will bypass these laws by purchasing products through countless unregulated deals that can easily be found on platforms like TikTok and Snapchat.

To date, no state has successfully implemented a PMTA directory. Legal challenges and enforcement difficulties have plagued these efforts, underscoring the impracticality and inefficacy of such regulations. For instance, a county judge put enforcement of Louisiana's PMTA directory on hold last month. Prior to the Louisiana law being enjoined, our trade group received multiple reports of vaping products being sold out of car trunks in the parking lots of smoke shops.

Youth Vaping Has Plummeted as Adult Use Has Grown

Contrary to the narrative of a vaping epidemic, the rate of youth vaping has plummeted by 60% since 2019, while usage of vaping by adults has surged by over 25%. This growth is predominantly attributed to adults opting for flavored disposable vaping products, highlighting a shift towards safer alternatives to smoking.

AMERICAN VAPOR MANUFACTURERS

In fact, youth vaping is at its lowest rate nationally in a decade. Please keep this in mind when proponents claim that these "new" disposable vaping products are targeted at kids.

Inappropriate Marketing Does Not Justify Broad Bans

In hearings across the country, proponents of PMTA registries have displayed photos of inappropriately marketed vaping products to suggest that action is needed. We support targeted legislation to eliminate market outliers. However, we believe this can be accomplished without resorting to overreaching measures that harm responsible businesses and consumers.

Questions for Proponents:

- (1) If disposables are indeed impacting cigarette sales negatively, isn't it logical to infer that Altria anticipates a rebound in cigarette sales should PMTA registries be enacted and enforced vigorously?
- (2) If the FDA denies the remaining pending PMTAs, how is enforcement going to work with just \$3,000-\$5,000 in annual fees?
- (3) Have any states successfully curtailed illicit sales via social media platforms?
- (4) How will adult constituents and voters respond to being told they can buy cigarettes, but not a fruit-flavored vape?

Conclusion

The American Vapor Manufacturers and Maryland's small businesses are eager to engage in meaningful discussions to devise fair and effective regulatory frameworks for vaping products. We firmly oppose HB 1033 and kindly request your support in defeating this bill.

Thank you for considering our testimony.

Sincerely,

Gregory Conley

Gregory Conley, JD, MBA President, American Vapor Manufacturers 231 Church Road, Medford, NJ 08055 (609) 947 – 8059 gconley@theavm.org

E-Cigarettes Authorized by the FDA As of Jan. 2024, these are the only e-cigarettes authorized to be sold in the U.S.



Manufacturer	Product Name
Logic Technology Development	Logic Regular Cartridge/Capsule Package
Owned by Japan Tobacco	Logic Vapeleaf Cartridge/Capsule Package
International	Logic Vapeleaf Tobacco Vapor System
	Logic Pro Tobacco e-Liquid Package
	Logic Pro Capsule Tank System (1)
	Logic Pro Capsule Tank System (2)
A.A.	Logic Power Tobacco e-Liquid Package
WINGS Filter Typped	Logic Power Rechargeable Kit
NJOYLLC	NJOY DAILY Rich Tobacco 4.5%
Owned by Altria	NJOY DAILY EXTRA Rich Tobacco 6%
FILTER CIGARETTES	NJOY ACE Device
	NJOY ACE POD Classic Tobacco 2.4%
This moreon safer. Nothing about this eigenet	NJOY ACE POD Classic Tobacco 5%
A CLASS & CLARETTES	NJOY ACE POD Rich Tobacco 5%
R.J. Reynolds Vapor Company	Vuse Vibe Power Unit (1)
Subsidiary of R.J. Reynolds	Vuse Vibe Tank Original 3.0%
Tobacco	Vuse Vibe Power Unit (2)
	Vuse Solo Power Unit
	Vuse Replacement Cartridge Original 4.8% G1
	Vuse Replacement Cartridge Original 4.8% G2
DISCONTINUED	Vuse Ciro Power Unit (1)
DISCONTINUED	Vuse Ciro Cartridge Original 1.5%
DISCONTINUED	Vuse Ciro Power Unit (2)

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Position: UNF

Ronald A. Ward Jr., Esq. Owner The Vapers' Edge 8116-A Harford Road Parkville, MD 21234 443-725-5251 thevapersedge@gmail.com

Written Testimony

To: Maryland House Economic Matters CommitteeFrom: Ronald A. Ward Jr.Date: February 20, 2024Re: Opposition to Maryland House Bill 1033

I. Introduction

My name is Ronald Ward and I am a life-long resident of Maryland. I have been an Electronic Smoking Device (hereinafter "ESD") user for over 14 years, an ESDs advocate for over 12 years and have owned an ESD store (vape shop) in Baltimore County, MD for the past 10 years.

This Bill would devastate Maryland Vape Shop businesses, eliminate nearly all ESDs from the legitimate market, create an ESD black market (in addition to the existing online black market) and force former smokers back to the deadly habit of smoking. It would also bolster the sales of cigarettes and other combustible tobacco that is almost primarily sold in convenience stores. These convenience stores make minimal income from and sell a very limited variety of ESDs while most of their tobacco profits result from the sale of combustible tobacco products. That is the reason why convenience stores and big tobacco companies are in favor of this Bill. Actually, the big tobacco companies are shopping this legislation in most of the country. This is nothing more than an attempt to destroy the existing ESD industry in Maryland in favor of a handful of big tobacco ESD products. Keep in mind that big tobacco companies derive a very small percentage of their profits from the sale of ESDs. Furthermore, the big tobacco companies have already admitted that ESDs are significantly cutting into their cigarette profits. Therefore, the utter elimination of ESDs would benefit their deadly cigarette businesses.

II. Overview of House Bill 1033

HB 1033 proposes an effective prohibition on virtually all vaping products currently on the market. It is the product of big tobacco companies looking to crush the ESD market, sell more cigarettes and make ESD products unappealing. This Committee will basically hand over the ESD industry in Maryland to big tobacco companies and organized crime if this Bill becomes Law.

As to its substantive issues, in Section 16.7-302, this Bill sets forth a regulatory and fiscal framework that is completely insurmountable not only for ESD businesses in Maryland but also for the State itself. For the sake of brevity, I am available for an in-depth discussion of the language referred to in the previous statement.

The Bill demonstrates a fundamental misunderstanding of the very industry and its consumers that it seeks to regulate.

This fact is clearly illustrated in the last 4 lines of Section 16.7-306 which read:

"The penalties in paragraph (1) of this subsection (which, BTW is a misdemeanor criminal charge) do not apply to a person who possesses less than \$100 worth of Electronic Smoking Devices solely for personal consumption and not for a resale to a consumer". I have vaped for 14 years and regularly carry well more than one hundred dollars (\$100.00) worth of ESDs solely for personal consumption. Incidentally, as I draft this Bill, I am vaping an ESD that, with all its components plus liquid total approximately, two hundred dollars (\$200.00) not including tax. I also always carry a backup which, depending upon the device and additional liquid, usually total the same price. Also, how does an enforcement officer know the retail price of an ESD?

The bottom line is that HB 1033 will eliminate over 95% of nicotine vaping products available at Maryland specialty retailers. This will disproportionately benefit large tobacco companies by decimating their competition.

III. Incomplete, Arbitrary and Caprecious FDA PMTA Process and Lawsuits

The FDA PMTA process has been fraught with problems since its inception. Its disorganized, expensive and completely unfair handling of this process is inexcusable. Also, it is a process that, at this time, is far from complete. Furthermore, the FDA has arbitrarily denied marketing orders for nearly 1 million products and is failing to move forward with authorizing hundreds of thousands of other products.

The process is so flawed that a United States Court of Appeals recently ruled that the process, for many reasons, is "arbitrary and capricious". Therefore, they remanded to the FDA in order for the agency to correct these serious problems with the PMTA process. There are also hundreds of thousands of applications that have not been reviewed. Of course, many companies have filed suit against the FDA and there are more to come in the future. Therefore, this proposed legislation is not ripe and this Committee should issue an unfavorable report for HB 1033.

IV. Consequences for Public Health and Consumer Choice

There is a reason why Altria—America's largest cigarette company—is such a fervent advocate for registries or "certification", as it is named in this Bill. Last October, they blamed ESDs for causing their cigarette sales to decline faster than anticipated. Altria's advocacy suggests a strategic interest in making quality vaping products less accessible, potentially driving adults back to smoking cigarettes.

V. No State Has Successfully Implemented a PMTA Registry

To date, no state has successfully implemented a PMTA registry. Legal challenges and enforcement difficulties have plagued these efforts, underscoring the impracticality and inefficacy of such regulations. For instance, a county judge put enforcement of Louisiana's PMTA registry on hold last month.

Prior to the Louisiana law being enjoined, I learned of disturbing reports of vaping products being sold out of car trunks in the parking lots of tobacco shops. That is in addition to the easy availability of these products through social media channels like TikTok and Snapchat. Furthermore, ESDs are readily available to consumers online despite a Federal law (the PACT Act), which prohibits the shipping of ESDs from retailer to consumers in the United States. Instead of focusing their attention on law-abiding, tax-paying legitimate businesses, maybe the drafters should focus on the bad actors?

VI. Youth Vaping Has Plummeted as Adult Use Has Grown

Contrary to the narrative of a vaping epidemic, the rate of youth vaping has plummeted by 60% since 2019, while usage of ESDs by adults has surged by over 25%. This growth is predominantly attributed to adults opting for ESDs, suggesting a significant shift from smoking to vaping.

VII. Conclusion

Thank you for considering my testimony. For the reason set forth above, I recommend that the House Economic Matters Committee issue an unfavorable report for House Bill 1033. As stated previously, this Bill would absolutely destroy the mom-and-pop ESD businesses in favor of big tobacco companies, lone criminals, organized crime and illicit online sales. It would certainly force me to close the doors of my legitimate, law-abiding business that I worked a decade to build. If this Committee has any inquiries or requests for supporting documentation, please feel free to contact me and I will promptly provide said documents. I am also open to a verbal dialogue with any member of this Committee regarding HB 1033.

HB1033_MRA_UNF.pdf Uploaded by: Sarah Price Position: UNF

MARYLAND RETAILERS ALLIANCE

The Voice of Retailing in Maryland



HB1033 Business Regulation - Electronic Smoking Devices Manufacturers – Certifications Economic Matters Committee February 20, 2024

Position: Unfavorable

The Maryland Retailers Alliance (MRA) has serious concerns about the overall impact of a slate of proposals introduced this year regarding tobacco sales. It appears that the legislature intends to use regulation as a vehicle for removing tobacco from the state through a combination of policies including high tax rates and retail sale prohibitions. We have chosen to address several bills in one document as these bills are scheduled to be heard in separate committees and on separate dates, and we want to ensure that each body is considering the full scope of these proposals and the impact of these policies as a package rather than passing them in a vacuum.

Our membership does not disagree with an intent to address minors' use of illegal products, but the manufacturing and sale of tobacco products is already a highly regulated industry. Age-restriction laws are in place to keep these items out of the hands of children, and consumers in Maryland face some of the highest taxes on tobacco in the country at \$3.75 per pack of 20 cigarettes – higher than all of our neighboring states: Virginia (\$0.60 per pack), West Virginia (\$1.20 per pack), Pennsylvania (\$2.60 per pack), Delaware (\$1.20 per pack), and even Ohio (\$1.60 per pack), North Carolina (\$0.45 per pack), and New Jersey (\$2.70 per pack).

Restricting or prohibiting the sale of products is often well-intentioned and seems like the simplest solution to curb tobacco use: ban or make it difficult for tobacco customers to buy their preferred products, and they will stop using them. We know from cases around the country where governments have passed local flavored tobacco bans that this is not the case. Customers who cannot conveniently purchase these products in Maryland will go to another state to buy the items that they are looking for. There are over 1,600 tobacco retailers within ten miles of Maryland's border in neighboring jurisdictions and no Marylander lives farther than 35 miles from a tobacco retailer across the state line. Users who face a barrier to travel will simply get their products online or illegally from the black market.

We support a regulated industry, and that includes making sure that the products that are available to customers are vetted items. Efforts to curb use that could result in increased black market activity may be detrimental to the health of adult consumers of tobacco products, and we would respectfully urge the Committees to strongly consider this when discussing these bills.

HB1033/SB987 Business Regulation - Electronic Smoking Devices Manufacturers – Certifications

HB1033 would require the establishment of a directory of electronic smoking devices that have been approved for sale by the Food and Drug Administration (FDA), ostensibly in an effort to reduce the proliferation of illegal products in the market. We do not oppose the goal of this legislation but there are issues with the bill as proposed.

The directory created by HB1033 would allow the sale of products that have already received approval for sale by the FDA but the bill does not include any statutory requirement to update the directory as new products are approved. This omission fails to address products that were submitted for federal consideration by the September 9, 2020 deadline but which have not yet received a final decision from the FDA.

A separate bill being considered this year, HB1197, proposes a similar directory but requires the Office of the Attorney General to update the directory as needed in order to correctly reflect approved products. Our members have expressed a preference for HB1197 over HB1033 due to this difference.

We would urge an unfavorable report on HB1033.

HB844/SB582 Business Regulation - Cigarette, Other Tobacco Product, and Electronic Smoking Device Retailers - Nicotine Replacement Therapy Products (Make Quitting Convenient Act)

HB844 would require any retailer that sells tobacco products to also sell nicotine replacement therapy products and to post signage in stores. It is inappropriate for the legislature to mandate that retailers carry specific products and to even establish parameters around ordering and stocking timelines, which can vary widely between individual business practices.

In addition to this overreach, the signage requirements in HB844 would be burdensome for businesses. "Real estate" space for notices and signs in stores is a tight market, and customers are already overwhelmed with signs on a multitude of topics in aisles, at the entrance of stores, and at the point of sale, especially in stores like pharmacies, grocery stores, and convenience stores that sell a wide variety of items. A federal order already exists which mandates that businesses post signage about the dangers of smoking, and this should be sufficient to suggest changes to consumer behavior.

We would urge an unfavorable vote on HB844.

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HB1197 Business Regulation - Electronic Smoking Devices Manufacturers – Certifications

HB1197 would require the establishment of a directory of electronic smoking devices that have been approved for sale by the Food and Drug Administration (FDA), ostensibly in an effort to reduce the proliferation of illegal products in the market. Unlike HB1033, HB1197 would require that the directory be updated to reflect products that have been newly approved for sale by the FDA, as many items were submitted for review by the federal deadline in 2020 but have yet to receive final determination. A similar bill was recently passed in Virginia and HB1197 would create a consistent market between Maryland and our close neighbor, decreasing the likelihood of consumers crossing the state line in search of specific legal products. Our members have expressed a preference of HB1197 over HB1033 for these reasons.

We would support a favorable report on HB1197.

HB1180/SB1056 Cigarettes, Other Tobacco Products, and Electronic Smoking Devices -Revisions (Tobacco Retail Modernization Act of 2024)

HB1180 would, among other things, prohibit retailers with a pharmacy permit from selling tobacco products. As a proponent of the free market, we strongly oppose this prohibition which would restrict access to legal, regulated products for purchase by consenting adults. This is of extremely serious concern to not only our retail chain drug stores but also grocery stores in Maryland that provide a pharmacy counter in their community. It is unclear in the bill whether this prohibition on sales in pharmacies would apply only to the pharmacy area in grocery stores, or if retailers would be restricted from selling any tobacco products anywhere in a store that also includes a pharmacy counter.

Marylanders are accustomed to being able to buy a variety of goods outside of the primary categories of food and medicine at both grocery stores and pharmacies, with retail pharmacies often meeting consumer needs by operating as a small general store in many communities. As noted in our introduction, restricting access to legal products may only drive consumers to shop in jurisdictions outside of Maryland or to purchase their desired items through illegal, unregulated channels. We strongly oppose this proposal and believe that it would harm the business community in Maryland without effectively reducing tobacco use in the state.

We would urge an unfavorable vote on HB1180.

HB1073 Tobacco Tax - Cigarettes - Rate Alteration

HB1073 would increase the sales tax rate on cigarettes from \$3.75 per pack of 20 cigarettes to \$4.50 per pack, and from 17.5 cents per cigarette in a larger pack to 22.5 cents per cigarette. As noted in our introduction, Marylanders already pay a higher tobacco tax than consumers in any of our immediately neighboring states and beyond, and can reach cigarette retailers in any of those states by driving less than 40 miles. This

regressive tax would primarily impact tobacco use for consumers who cannot travel even that simple distance, and could result in higher sales in the black market rather than any actual reduction in tobacco use. Increasing the tax on cigarettes by almost \$1.00 per pack would increase "border bleed" sales and harm businesses by greatly increasing the price of legal, regulated products for adult consumers.

We would urge an unfavorable report on HB1073.

HB1414 Electronic Smoking Devices - Licensure, Indoor Use, and Taxation – Alterations

HB1414 would, among other things, increase the sales tax rate on electronic smoking devices from 12% to 30%. As noted in our introduction, regressive tax increases such as this merely encourage consumers to cross Maryland's very close borders to purchase their desired products. Increasing prices as a method to encourage a change in consumer behavior is inappropriate for these items, as is using the consumption of certain products as a method of increasing tax revenue. Increasing this tax would harm businesses and increase prices for legal items for use by adults in Maryland. Other bills have been introduced which would update the Clean Indoor Air Act to restrict the indoor use of electronic smoking devices, and which have not been opposed by MRA.

We would urge an unfavorable report on HB1414.

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MVA HB1033 Opposition.pdf Uploaded by: Tyler Bennett Position: UNF

Maryland Vapor Alliance

Opposition to HB 1033

On behalf of the Maryland Vapor Alliance (MVA), who represents over two hundred small business vape shops in the state of Maryland, we oppose House Bill 1033.

Per the CDC's most recent research report, Maryland has the second lowest cigarette use in the United States. This is a result of safer harm reduction options available and the vape shops that help keep these customers off combustible cigarettes. This bill completely turns the clock back and plays right into the big tobacco initiatives.

If this bill is passed in its current form, just twenty closed-system big tobacco products will remain on the shelf, and all other products will be illegal. These products are high nicotine items, only available in tobacco and menthol flavors.

Customers who use open system vape products and are on lower milligrams of nicotine such as 3mg or 6mg would have the following options:

- They can convert to one of the big tobacco conglomerate's high nicotine products at 50mg+
- They can go back to smoking cigarettes.
- They can find their products on the black market or go to another state.

This bill is a win for big tobacco, who have their lobbyists pushing this bill across multiple states.

Data continues to show that small business vape shops in Maryland have a clean record in terms of underage compliance checks. This legislation would ensure that those responsible retailers would close their doors, leaving only high nicotine products sold by big tobacco companies on shelves elsewhere.

Recently in January, the U.S. 5th Circuit Court ruled against the FDA regarding their pre-market tobacco application (PMTA) process. Small business vape shops and manufacturers filed this suit after having their PMTA denied by the FDA and were awarded an injunction before the ruling came out a few weeks ago. The circuit court found the PMTA process to be "fatally flawed," "arbitrary and capricious," and "sent manufactures of flavored e-cigarettes on a wild goose chase." The FDA

will now have to revamp its entire process and re-review the thousands of applications that they unfairly denied. This followed another ruling against the FDA from the U.S. 11th Circuit Court along similar circumstances. Additionally, there are a number of other cases currently making their way through the federal court system, and ultimately the issue may end up in the U.S. Supreme Court.

In conclusion, this legislation stands to only benefit the three Big Tobacco companies whose high nicotine products would remain on the shelves in Maryland.

Contact: Tyler Bennett, Compass Advocacy <u>tbennett@compassadvocacy.com</u> Candice Gott, Maryland Vapor Alliance <u>candicedeane@hotmail.com</u>