

The We Card Program, Inc.



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RE: FDA-2019-D-0661-0001

Modifications to Compliance Policy for Certain Deemed Tobacco Products; Draft Guidance for Industry

To Whom It May Concern:

On behalf of the *We Card Program, Inc.*, sponsor of the *We Card* training and education program, we welcome the opportunity to provide our views on the Food and Drug Administration's ("FDA") request for comments on draft guidance entitled "Modifications to Compliance Policy for Certain Deemed Tobacco Products" (the "Draft Guidance").

We Card is a Virginia non-stock corporation qualified as tax exempt under Section 501(c)(4) of the Internal Revenue Code. Our mission is to provide training and education to retailers and assist them in their efforts to prevent the sale of age-restricted products and to comply with federal laws, FDA regulations and state and local laws.

We Card shares FDA's concern over the alarming increase in youth use of electronic nicotine delivery systems (ENDS), such as e-cigarettes and vaping products.

FDA noted in its Draft Guidance that a variety of reports, studies and data informed its decisions to "prioritize enforcement" as reflected in the Draft Guidance. Our comments submission seeks to further inform FDA on:

- Bricks-and-mortar retailer efforts at identifying and denying minors' attempts to purchase ENDS and any FDA-regulated tobacco product.
- Additional evidence and information available -- within FDA-cited research -- and in research not referenced by FDA. (There is additional evidence not referenced in FDA Draft Guidance. Some of it is within the same research or studies cited by FDA.
- Tools or actions available to FDA, but not undertaken.
- Request for greater detail of specific requirements of retailers

What are bricks-and-mortar retailers doing to prevent minors' access to ENDS and other FDA-regulated tobacco products?

Many retailers are training employees, using age-calculation tools, checking employee performance through internal compliance checks (mystery shopping), and visually re-enforcing their efforts with customer-facing (and cashier-facing) signage.

We Card works with retailers both directly with retail chain headquarters and virtually through online interactions with smaller store operators and single store operators. Retailers use turnkey *We Card* services or selectively add-on services, tools or resources to enhance their internal compliance efforts.

[We Card's online training](#) meets and exceeds the curriculum and reporting suggestions found in [FDA Guidance for Tobacco Retailer Training Programs](#). Retailers train employees using *We Card's* training while many more use elements of *We Card's* curriculum in tandem with company programs. Over the years, *We Card* has directly trained nearly 500,000 retail employees, many of whom report going onto train others in their store.

Age-restricted product retailers, especially retail chains, check employee performance through mystery shopping to ensure employees are indeed asking for identification of under 27 year old customers as FDA requirements specify.

Annually, retailers order in-store *We Card* materials of which more than three-fourths are training and education materials and tools that are out-of-sight of public view but play a critical role to further the fundamental task of identifying and denying minors' purchase attempts of ENDS, tobacco or other age-restricted products.

Some retailers replenish their *We Card* needs annually, some every few years depending upon how they complement their internal programs. Categorized by functional utility, *We Card* has fulfilled retailers' requests for these tangible items over the years:

Age Calculation Tools:	4.1 million
Training Tools:	6.8 million
Visual Reminders:	5.6 million

Digital *We Card* materials and cloud-based or app-living resources, including online age calculation tools, law summaries and more are downloaded, distributed and infused into the retail environment.

While not enforced nor recommended by FDA, *We Card* trains and educates retailers to spot and deny adult purchases on behalf of minors. Many states prohibit this adult-for-minor purchase, but such prohibition is rarely enforced. Nevertheless, this is another step retailers using *We Card* training have taken to address the ways minors attempt to gain access to age-restricted products.

In one form or another, elements of the *We Card* program are utilized in 80-90% of tobacco-selling retailers (and many of those retailers sell ENDS products). Retailers use of *We Card* services and *We Card*-like services should be recognized and factored into the dynamics of the overall issue of youth access to ENDS and tobacco products.

Additional evidence and information

What does the official government data show of retailers' compliance?

The FDA, and separately each state government, conducts compliance checks using minors (often 15-17 year olds) to attempt to purchase tobacco or ENDS from bricks-and-mortar retailers.

The long time standard bearer of compliance rates is the “retailer violation rate” reported in “Synar Report” produced by the Substance Abuse and Mental Health Services Administration (SAMHSA). Since 1997 SAMHSA has reported on each state’s compliance with the Congressional requirement that each state meet a retailer violation rate of no more than 20% by the year 2003 and every year thereafter. In 1997 SAMHSA reported a national weighted average of the retailer violation rate to be 40%.

The *We Card* Program launched its services for retailers and completed its first year in 1996. Retailers – and all involved in the manufacturing, wholesaling and retailing of tobacco – embraced the “responsible retailing” of tobacco products mission of the *We Card* program. Retailers use of “*We Card*” took many forms (from internally-developed retail chain training programs to use of *We Card* training services, mystery shopping, in-store signage, and age calculation tools, such as the *We Card* Age of Purchase Calendar). By the year 2000, the Synar national weighted average retailer violation rate met the goal of equal to or less than 20%.

In 2014 as e-cigarettes further entered the retail market, *We Card* trained and educated retailers to deny minors’ attempts to purchase them. In this way, retailers have led the way while state governments and FDA regulations caught up to the retailer norm of restricting sales to minors.

Today, the most recent SAMHSA Synar report (FFY 2018) indicates a 9.6% retailer violation rate in FFY 2018 (which is 50% lower than the 20% goal).

FDA Draft Guidance mentions an intent to “prioritize enforcement” towards the lion’s share of retail stores (convenience stores, grocery stores, drug stores, supermarkets, etc.) who do NOT ask for ID at the door and do NOT operate as if the store is an adult-only facility. Many of these retailers are the same ones that have “prioritized compliance” with age-restricted product laws for the past 22 years.

The most recent 9.6% retailer violation rate reported by SAMHSA seems relevant here. We recognize not every state Synar compliance check program includes ENDS as one of the products attempted to be purchased by minors. Of 40 states where we found publicly available copies of their FFY 2018 or 2019 Synar Report submissions to SAMHSA, we note that 19 states include ENDS products during their compliance

checks. The low 9.6% retailer violation rate and a 3-year downward trend of the Synar Report retailer violation rate is positive news.

The question is where are youth predominantly accessing ENDS.

The answer can be found in new and existing research. Meanwhile, publicly-available FDA enforcement data of over a million compliance checks of retail stores – with 750,000+ checks using minors attempting to buy FDA-regulated products -- shows an 8-year average violation rate of 12.5% (or an 87.5% compliance rate) as calculated by the *We Card* Program. If compared to the Synar Report's goal of 20% or less, that 12.5% is well below the Congressional target. While an even better compliance rate is desirable, retailers are doing their part. For the last 6 months (Oct 2018 to March 2019), more than 66,000 FDA compliance checks show a 12.4% violation rate. The data does not show a rise in violations that corresponds to a rise in youth use of ENDS.

FDA does not consider its compliance data statistically valid yet the very large sample of 750,000 checks to date does provide a perspective of what is occurring with compliance.

Taken together, both the Synar Report data and the FDA enforcement data do not show increases in violation rates, and do not provide evidence to account for increased youth access to ENDS from bricks-and-mortar retailers.

The FDA reported National Youth Tobacco Survey (NYTS) data provides another glimpse at compliance and possible answers to youth access to ENDS.

FDA indicates that the NYTS 2018 data shows under 18 year-old ENDS users reported getting or buying e-cigarettes during the past 30 days at these sources:

- 8.4% a gas station or convenience store
- 14.8% a vape shop or other store that only sells e-cigarettes
- 6.5% on the Internet

While there is always room for improvement, the NYTS offline (bricks-and-mortar retailer) numbers are below the Synar Report 20% goal, with the largest store volume group of gas station or convenience store below the Synar Report's FFY 2018 9.6% retailer violation rate.

What is missing from this 2018 NYTS data reported by FDA (footnoted by FDA as manuscript in progress) are the additional multiple choice answers on youth access, including "how" they obtained ENDS or tobacco.

In prior year NYTS surveys, those answer options included what is commonly referred to as "social source" access, such as:

- I had someone else buy them for me
- I asked someone to give me some
- Someone offered them to me
- I bought them from another person
- I took them from a store or another person
- I got them some other way

Since this data wasn't reported or referenced in FDA Draft Guidance, it is our view that FDA would benefit from an examination of the complete NYTS data as it contemplates appropriate strategies to address the rise in youth ENDS use.

The same is true for the Population Assessment of Tobacco and Health (PATH) study FDA references on youth flavor preferences of ENDS products. Other PATH data from Wave 2 and 3 identifies varying sources similar to the missing 2018 NYTS "social source" information. This data is available to inform FDA (and others) on where the points of access are for 15-17 year olds. PATH Wave 3 data shows nearly 75% of e-vapor youth access were from the similar "social source" categories while "bought from store" was 14.9%.

Further, in FDA cited research titled, *"How Do Adolescents Get Their E-Cigarettes and Other Electronic Vaping Devices?"*, FDA identifies online purchases at 32.2% per FDA footnote 28. While not referenced in FDA Draft Guidance, this same study identified "convenience, gas or liquor store" at 5.6%. That is a positive number in the context of the Synar program's goal of no more than 20%, and another data point of evidence reflecting on bricks-and-mortar retailers "prioritization of compliance."

What is also revealing in the same *"How Do Adolescents"* study – but not referenced in the Draft Guidance – is the data on the other sources. Those numbers represent 68.7% of the sources 15-17 year olds identified as their "primary" source of vaping devices. The research categorized them as:

- 16.3% Bought from another person
- 15.0% Gave money to someone else
- 4.5% Bought from flea market, swap meet, the street
- 14.3% Received as gift
- 4.9% Got from parent
- 11.6% Other source
- 2.1% Stolen
- 68.7%

Many of these primary sources fall into the same "social source" category of the PATH studies and the historical NYTS studies mentioned earlier.

Looking back a year earlier to the most recent CDC Youth Risk Behavior Survey (YRBS) 2017 study, released in June 2018, the data shows commercial access identified as 13.6% (bought them in a store) and 6.7% (got them on the Internet.) The balance of 79.8% are varying forms of the same "social source" points of access.

FDA may only focus on commercial business access avenues (retail stores and Internet sales) and not address all sources of ENDS or tobacco products by minors but it is clear that the evidence of "social sources" access needs to be recognized and addressed in the context of the reported epidemic increase in youth use of ENDS.

It is incumbent among all stakeholders to further work to reducing retail violations, improve compliance and begin to address the predominance of the multi-faceted "social source" issue of ENDS and tobacco products.

Tools or actions available to FDA, but not undertaken

FDA has a two-tiered fine and penalty schedule for retailers found in violation of the Tobacco Control Act for violations of selling tobacco (and now ENDS products, since FDA deemed to be considered tobacco products in 2016).

However, all retailers, including those with zero efforts at training employees to identify and deny illegal sales to minors, are provided the lowest tier fine and penalty schedule as if they had what the Act reserved only for retailers implementing an “approved” training program.

Finalizing regulations or guidance on establishing the definition and/or requirements of an FDA approved training program, and thus, rewarding retailers who implement a program with the reduced fine/penalty schedule (and more stringently penalizing those who do not) is a tool readily available to FDA to further improve retail compliance and reduce commercial access to FDA-regulated products.

We Card offers individual retail employee training, refresher training, and manager training. It is cloud-based, easily accessible and licensed to retailers to incorporate into their own eLearning systems as well.

We believe FDA “approved” Tobacco Retailer Training Programs will incentivize retailers to train employees to identify and deny minors’ attempts to purchase FDA-regulated products. It can only help combat the commercial access element of the overall youth use issue. We respectfully request FDA finalize an “approved” Tobacco Retailer Training Program and approve *We Card’s* training program as one meeting the “approved” standard.

Request for greater detail of specific requirements of retailers

FDA Draft Guidance is not overtly clear on what it means for FDA to “prioritize enforcement.”

The Draft Guidance indicates “FDA intends to prioritize enforcement” for flavored ENDS products (other than tobacco-flavored, mint-flavored, and menthol-flavored) sold in locations that minors are able to enter at any time.

This can be interpreted to mean retailers with stores where minors may enter (such as most stores in the marketplace, like convenience stores, grocery stores, etc.) are banned from selling those products. It can also be interpreted to mean FDA will direct more enforcement activities (such as compliance checks) toward those store types.

This lack of clarity can lead to both ambiguity and confusion.

Prior FDA guidance has provided very specific retailer requirements while this draft lacks specificity. As a result, The *We Card* Program would find it difficult to recommend specific actions retailers must or could take to comply with the current information provided in the draft guidance.

We Card appreciates this opportunity to provide comments on FDA's Draft Guidance. If you have any questions or if we can be of any further assistance, please do not hesitate to contact the undersigned.

Sincerely,

A handwritten signature in black ink that reads "Doug Anderson". The signature is written in a cursive, flowing style.

Doug Anderson
President
The *We Card* Program, Inc.