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*An AACC/CAP Educational Newsletter for Toxicology Laboratories*

## Electronic Cigarettes:
### *Nicotine Delivery Systems Offer New Option, But Are They Safer?*

*By Jennifer Colby, PhD*

In 2003, the Chinese company Ruyan Group Holdings submitted a patent application for a novel nicotine delivery device. Aptly called an electronic cigarette, the device's small battery heats a solution to produce a nicotine-laden vapor that the user inhales. Ruyan filed for a patent in the United States in 2005. Nearly ten years later, electronic cigarettes have exploded in popularity, with almost 500 brands available worldwide and an estimated $3 billion in yearly sales. The scientific community's interest in electronic cigarettes has also exploded, with mentions in the PubMed database increasing exponentially (Figure 1).

Electronic cigarettes have many monikers, including e-cigarettes, e-cigs, vape pens, and electronic nicotine delivery systems (ENDS). ENDS come in many styles, ranging from disposable devices resembling traditional tobacco cigarettes (TC) to refillable personal vaporizers that look more like a flashlight. ENDS are available at brick and mortar establishments, including convenience stores, but are also sold over the Internet. Initially, ENDS manufacturers tended to be small companies with no history in the tobacco products market. Recently, however, large tobacco companies have begun adding ENDS to their product portfolios.

#### How ENDS Work

Most ENDS are airflow-activated, battery-powered atomizers. Inhaling on the mouthpiece activates the airflow sensor, which triggers the battery-powered atomizer to heat the nicotine solution to approximately 55 °C and produce a vapor containing micro-droplets of nicotine. The user inhales the nicotine into the lungs. The process is referred to as "vaping."

The amount of nicotine a device delivers depends on many variables, including the battery's voltage and the design of the mouthpiece and vaporization chamber. Battery voltage and device design vary from one manufacturer to another, thus ENDS vary in the amount of nicotine delivered per puff.

Many factors influence the decision to vape or to vape rather than smoke. Studies of ENDS users have found that they perceive vaping to be healthier, cleaner, cheaper, and more modern than smoking (1). In addition, ENDS can circumvent smoke-free policies in workplaces and businesses. Though most ENDS users are current or former TC smokers, a 2103 report by the Utah Department of Health found that nearly one-third of ENDS users had never used TCs (2,3). Although ENDS are not marketed as smoking cessation tools, some users claim they are more effective for this purpose than traditional nicotine replacement therapies. Scientific studies on the utility of ENDS for smoking cessation are limited, and further work is needed.

#### Content of ENDS Solutions

Though the ingredients vary by brand, ENDS refill liquids typically contain a vehicle, nicotine, and flavoring agents. The vehicle, which makes up the majority of the solution by volume, is most often glycerol or propylene glycol. Both compounds are listed on the Food and Drug Administration's (FDA) Generally Recognized as Safe (GRAS) list for use as food additives, but their safety in vaping solutions has not been studied. In a 2009 study, the FDA

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## Inside...

# ENDS Offer New Option

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found that one type of e-cigarette sold in the U.S. contained diethylene glycol, a cheaper compound that is often substituted for the safer glycerol. Diethylene glycol has been detected in toothpaste imported into the U.S. from China (4). Many ENDS refill solutions are manufactured in China, and one study found that almost 25% of ENDS refills did not include a list of ingredients on the label (5).

Nicotine, the most widely known of the tobacco alkaloids, is present at varying concentrations in ENDS refills. Some brands sell refills labeled with a nicotine concentration, others sell refills with a low-medium-high designation. Comparisons of low-medium-high solutions from different brands revealed that the concentrations varied widely (5–7). Even solutions labeled with a concentration did not always contain what the label stated (6,7).

Other tobacco alkaloids, including cotinine and anabasine, have been detected in vapor from some brands (8,9). An ENDS refill known as whole tobacco alkaloid e-liquid is specifically prepared to contain higher concentrations of the non-nicotine tobacco alkaloids (10).

Though the vast majority of ENDS refills contain nicotine, some solutions contain only flavoring agents and vehicle. Flavoring agents are minor constituents of most ENDS refill solutions, and many of these chemicals also appear on the GRAS list, but their safety has not been established in a vaping solution. ENDS e-liquids are available in a variety of flavors, ranging from fruit to candy to alcoholic beverages, many of which are expected to be highly attractive to young users. However, with the exception of menthol, flavored TCs have been banned in the U.S. since 2009, due to their appeal to children.

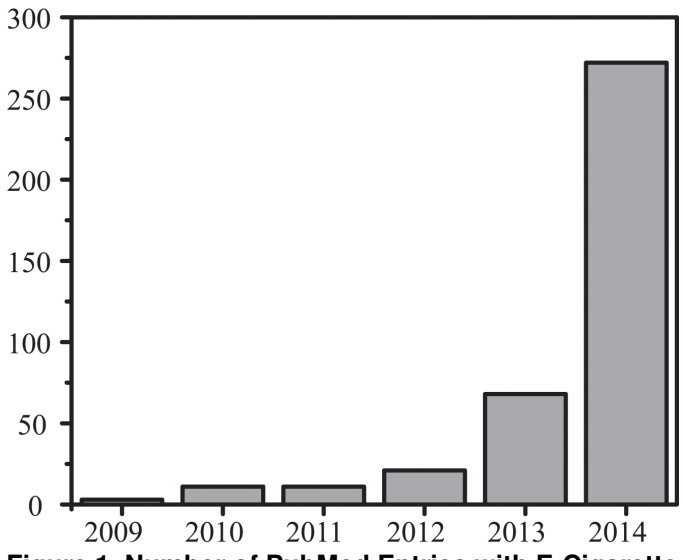


**Figure 1. Number of PubMed Entries with E-Cigarette in the Title**
Search terms included e-cigarettes, e-cigarette, and electronic nicotine delivery system. Database accessed December 2014.

### ENDS Regulation

Unique among nicotine-containing products, ENDS are not currently subject to regulation by the FDA. The FDA's Center for Tobacco Products regulates products such as TCs and chewing tobacco. A different branch of the FDA regulates traditional nicotine replacement therapies, like patches and nicotine gum, as pharmaceuticals. Because ENDS do not contain tobacco, and manufacturers aren't marketing them as cessation tools, they do not fall under the jurisdiction of either branch.

In April 2014, the FDA released a proposed rule with the intent to define ENDS and refill solutions as tobacco products, enabling the Center for Tobacco Products to regulate them. As of the end of 2014, the FDA had not taken any final action on this proposed rule change.

Because there are currently no federal rules, rules on ENDS sales vary by state. Though the sale of traditional TCs to minors is prohibited across the country, the same is not true for ENDS. As of November 2014, 10 states and the District of Columbia allow minors to purchase nicotine-containing ENDS (11) (Figure 2). Countries that have banned the sale and import of all ENDS have struggled to enforce the ban because ENDS are available online and can easily be shipped. If sales to minors are legal in some states, minors elsewhere in the country can simply purchase their ENDS products over the Internet.

### User Health Concerns

Despite the great interest in ENDS, data on the safety of the vapor is lacking. No clinical trials have been conducted in the U.S., largely due to the inability of device manufacturers to meet the FDA's requirements for approval of ENDS as an investigational new drug. Because of this, many of the studies allowed users to supply their own ENDS and refill solutions, which can confound the results. The literature that does exist supports the idea that ENDS vapor contains fewer tobacco-specific toxicants than TC smoke and is likely safer than TC smoke (7,12,13).

A recent letter to the editor in the *New England Journal of Medicine* demonstrated that variable-voltage ENDS operated at high voltage produce hemiacetal, a formaldehyde-releasing agent. Although the impact of hemiacetal on the respiratory tract is unknown, formaldehyde itself is a potent car-

cinogen. The authors estimate that vaping only 3 mL of ENDS solution per day would correspond to more than double the formaldehyde exposure of a 20 TC per day smoker (14). Acute effects of e-liquid refills containing propylene glycol as a vehicle can include contact dermatitis (15,16). The long-term safety of ENDS has not been established.

The most well-documented safety hazard associated with ENDS is accidental exposure to nicotine solutions. Calls to U.S. poison control centers regarding ENDS exposures increased 219% between 2012 and 2013, and are on track to double again between 2013 and 2014. Refill solutions are available in a variety of sizes and nicotine strengths, and many bottles contain more than 500 mg of nicotine.

From January to March of 2014, 651 nicotine exposures were reported to American poison control centers, and 50% of them occurred in children less than 6 years old (17). Exposures are especially concerning for children, for whom a 2-mg dose of nicotine can be toxic, and a 100-mg dose can be fatal. Sen. Bill Nelson (D-Fla.) introduced the Child Nicotine Poison Prevention Act of 2014, which urges the Consumer Product Safety Commission to require child-resistant packaging for nicotine-containing e-liquid refills, but the bill was not enacted (18).

## Public Health Problems

From a public health perspective, ENDS pose several problems. Arguably the largest threat is the renormalization of smoking behavior. After investing billions of dollars in smoking prevention and research, the U.S. has made gains in the war against smoking. Smokers now make up only 18% percent of the adult population, down from a high of 40% in the 1960s. The decrease can be attributed, at least in part, to making it difficult to smoke in public places. Many states have enacted comprehensive smoke-free laws, prohibiting smoking in public spaces as well as private workplaces and restaurants (11). Only three of the 26 states with comprehensive smoke-free laws ban ENDS use along with traditional smoking. More than 100 municipalities, including Los Angeles, New York City, and San Francisco, include bans on indoor ENDS use in their smoke-free laws (19). Regardless, ENDS are an attractive option for smokers who wish to imbibe in places where smoking is prohibited.

The second major public health concern is passive exposure to ENDS vapor, which can occur in public or in the home. Unlike TCs, ENDS produce vapor only when the user inhales, so second-hand smoke is produced only by the user's exhaled breath. Air exhaled by ENDS users has been shown to have a comparable amount of the nicotine metabolite cotinine as air exhaled by TC smokers (8).

Third-hand smoke refers to the deposition of nicotine and other tobacco-related toxicants on surfaces. Limited studies have identified ENDS as a source of third-hand exposure to tobacco toxicants. Nicotine from ENDS vapor can be deposited on various household surfaces, with the amount depending on the type of device and the type of surface (20). Exposure to chemicals from third-hand ENDS vapor is likely to occur via the oral or dermal routes, primarily in small children who engage in hand-to-mouth behavior.

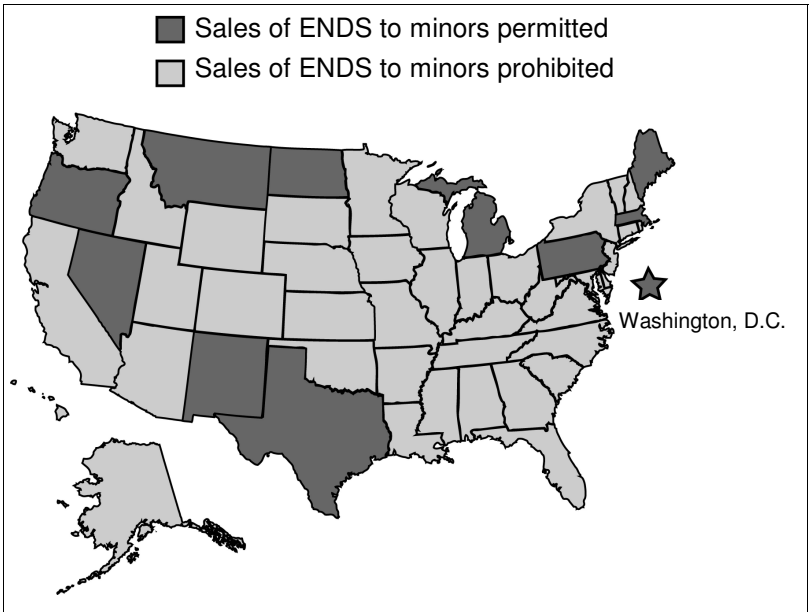


**Figure 2. States Where Minors Can Legally Purchase ENDS**
Adapted from reference 11.

## ENDS and Laboratory Testing

Accurate determination of smoking status is an important laboratory function. Smoking status is a critical factor for life insurance policies, with smokers paying significantly higher premiums than nonsmokers. Smoking status is also important to employers, both as a condition of hiring and for determining compliance with smoking-cessation initiatives. Many company-sponsored nonsmoking programs contain financial incentives, and companies can demand a refund from employees who have received a bonus but are found to be using tobacco.

Traditionally, laboratory tests have used the tobacco-specific alkaloid anabasine to distinguish active tobacco users from those using nicotine-replacement therapies. A urine sample that is positive for nicotine and its metabolite cotinine but negative for anabasine is consistent with use of nicotine replacement therapy, whereas a sample that is also positive for anabasine is consistent with tobacco use. ENDS refills are known to contain

anabasine, and ENDS users report testing positive for anabasine despite only vaping (9,21).

Further research is needed to determine whether ENDS and TC users show similar ratios of nicotine, nicotine metabolites, and anabasine in their urine. The legal issue of whether ENDS use is equivalent to smoking remains to be determined, but laboratorians should be aware that anabasine positivity could be consistent with ENDS use, and should educate their providers and patients accordingly.

**Summary**

Electronic nicotine delivery systems have been widely publicized in the media, but relatively little is known about their safety. Research into the health effects of ENDS use is ongoing, but is hampered by the lack of regulation of the ENDS industry. While ENDS users may experience fewer health effects than if they smoked cigarettes, ENDS use may still pose a threat to public health. Much of the concern with ENDS use rests on the appeal of the solutions to children, both in the context of accidental exposure and in the context of initiating smoking behavior. Laboratories that use anabasine as a marker of tobacco use should be aware that the nicotine solution in ENDS may contain anabasine, so ENDS users may be incorrectly identified as tobacco smokers.

## Learning Objectives

After completing this article, the reader will be able to summarize the pros and cons of policies on electronic nicotine delivery system use in the United States and to explain how ENDS use can affect interpretation of laboratory tests for cigarette use.

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# Preventing Opioid Abuse:
## *Prescription Drug Monitoring Programs Can Play Important Role*

*By Jacob T. Painter, PharmD, MBA, PhD and Daniel J. Cobaugh, PharmD, DABAT, FAACT*

In response to the epidemic of opioid abuse and misuse, almost all states have implemented prescription drug monitoring programs (PDMPs) to provide clinicians a new tool to prevent misuse of these drugs.

This epidemic has been described extensively in the literature over the past decade (1–7). A 2015 report from the Researched Abuse, Diversion, and Addiction-Related Surveillance (RADARS) System found that diversion and abuse of prescription opioid medications increased between 2002 and 2010, but this trend began to reverse between 2011 and 2013 (8). Despite these advances, data from the Centers for Disease Control and Prevention (CDC) indicate that 259 million analgesic prescriptions are provided each year and there are 46 opioid-related deaths per day in the United States (9).

A January 2015 article in *Morbidity and Mortality Weekly Report* revealed that 25% of pregnant women with private insurance and 33% of pregnant Medicaid enrollees filled a prescription for an opioid in each year from 2008–2012 (10). In addition, the reported progress in decreasing the misuse and abuse of prescription opioids has been accompanied by increases in heroin use (11).

### A Tool for Combating Misuse

Opioid abuse and misuse continue to be pervasive in the United States and efforts to counter it require multifaceted approaches with efforts by state governments, professional associations, medical boards, nonprofit organizations, clinicians, and the public (12). The prescribing and dispensing phases of the medication process are key points at which clinicians can decrease inappropriate access to opioid analgesics. PDMPs are widely adopted solutions that enable clinicians to intervene during prescribing and dispensing to decrease inappropriate opioid use.

The CDC and the Office of National Drug Control Policy consider PDMPs to be an important strategy to combat opioid abuse and misuse (13). PDMPs are state-level electronic databases to collect data on the use of opioids, other controlled substances, and some other drugs that are not controlled at the federal level but have potential for abuse. Currently, 49 states operate PDMPs, and the District of Columbia is in the process of implementing one. Missouri is the only state with no PDMP and no legislation pending (14).

### PDMP Goals

The specific goals of PDMPs vary from state to state, but the main ones are to: monitor prescribing and dispensing to individual patients, thereby providing treatment history to the health professionals responsible for a patient's care; provide information to law enforcement agencies and others to identify and deter prescription drug abuse and diversion; provide information to clinicians to help identify individuals at risk of addiction to a controlled substance; and provide information to researchers and public health officials about drug use trends and public health needs (15).

PDMPs can be either proactive or reactive. Proactive systems deliver information to prescribers or pharmacists when a patient meets certain prescribing or dispensing thresholds. Reactive systems can be queried at the discretion of the prescriber or pharmacist (16).

States differ in their requirements for prescribers or pharmacists to use PDMPs. When specific criteria are met, 21 states require prescribers to use the PDMP before they can prescribe specific controlled substances (16).

### PDMP Outcomes Data

The evidence that PDMPs can affect outcomes related to inappropriate opioid use is mixed. A 2011 study of deaths following opioid overdose found that PDMPs are not associated with decreased opioid mortality (17). However, a study from the RADARS System Poison Center Program and the opioid treatment surveillance databases found correlations between the presence of a PDMP and decreases in the number of poison center interventions and opioid overdose-related hospital admissions (18).

Although evidence of the effectiveness of

PDMPs at reducing opioid-associated deaths is not definitive, evidence of their ability to influence the behavior of prescribers, pharmacists, and patients is much stronger. Survey data has demonstrated that providers with access to a PDMP are likely to re-evaluate their prescribing practices based on the PDMP information. These studies have taken place in a variety of settings, including primary care (19), emergency departments (20), and substance abuse treatment programs (21), as well as in a variety of geographic areas (22–24).

Although there are fewer studies of pharmacists' attitudes toward PDMPs, their reactions have been generally positive. They have indicated that they use PDMPs primarily to reduce "doctor shopping" (25). One study showed that information-sharing after PDMP implementation reduced the length of investigations into possible doctor shopping from 156 days to 16 days (24).

The National Alliance for Model State Drug Laws and the National Safety Council have recommended PDMP best practices (26). These recommendations address interstate data sharing, expansion of authorized users, and compulsory use requirements by professional licensing status (26). Although there is a general trend toward increased interstate sharing and expansion of authorized users, some states have been slow to adopt recommendations that may have a large impact on practitioner-patient interactions, particularly compulsory use of PDMP.

## Conclusions

The epidemic of opioid misuse and abuse in the United States is associated with increased morbidity and mortality. As prescription drug monitoring programs continue to evolve, they are expected to play a critical role in decreasing inappropriate prescribing and dispensing of opioids.

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## For More Information

This article is adapted from a longer review by the authors in the *American Journal of Health-System Pharmacy*: Cobaugh DJ, Gainor C, Gaston CL, et al. The opioid abuse and misuse epidemic: implications for pharmacists in hospitals and health systems. Am J Health-Sys Pharm 2014;71:e82–e97.

## Learning Objectives

After completing this article, the reader will understand the implications of the increase in opioid prescriptions and recognize the role that PDMPs play in managing patients on chronic opioid therapy.

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# CAP Update

## *New Drug-Facilitated Crime PT Program Starts in June*

The College of American Pathologists (CAP) is offering a new proficiency testing program and is updating another program.

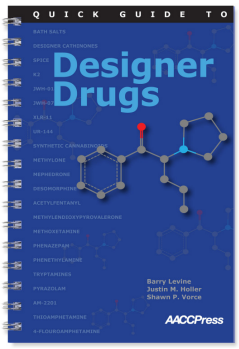
The Drug-Facilitated Crime Survey is a proficiency testing program for laboratories that perform testing in this field. It features drug targets at much lower concentrations compared with other toxicology surveys. The new survey offers a qualitative urine drug analysis with confirmation testing.

It consists of two shipments per year with three 25.0-mL urine specimens per shipment. The first mailing ships in June, so there is still time to order.

The Synthetic Cannabinoids and Designer Drug Stimulants Program addresses a field in which the chemicals involved are wide-ranging and constantly changing. To stay ahead of these changes, the CAP plans to modify the compounds in each shipment in accordance with the appearance and prevalence of new compounds. The current list of drugs in each PT challenge will be listed at www.cap.org at the Laboratory Improvement tab.

For more information or to order, please visit www.cap.org or call (800) 323-4040.

# New from AACC Press
## *Quick Guide to Designer Drugs*




Illicit drug chemists are modifying structures of abused drugs to circumvent legal restrictions and evade detection. The novel compounds they create have been dubbed "designer drugs." The *Quick Guide to Designer Drugs* reviews the major classes of these compounds. It includes discussions of designer cathinones (bath salts), synthetic cannabinoids (spice, K2), and designer phenethylamines and tryptamines, as well as analogs of benzodiazepines, ketamine, opioids, and phencyclidine. The popular designer cathinones and synthetic cannabinoids are subjects of their own sections.

The authors summarize data from postmortem cases, drugged driving cases, and in vivo and in vitro metabolism studies in the literature. They discuss the extraction procedures from biologic matrices and describe standard analytical methods—including immunoassay, gas chromatography-mass spectrometry, and liquid chromatography-tandem mass spectrometry—as well as more esoteric methods.

By Barry Levine, Justin M. Holler, and Shawn P. Vorce, the 204-page, spiral-bound book costs $24 ($20 for AACC members). It can be ordered online (www.aacc.org and click on the "Store" link) or by calling (800) 892-1400 or (202) 857-0717.

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