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Disposable Electronic Nicotine Delivery Systems (ENDS) and Underage Nicotine Addiction–A Survey of College Students

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OBJECTIVES/GOALS: To identify factors enabling growing underage consumption of disposable Electronic Nicotine Delivery Systems (ENDS) by understanding young adults'perceptions and patterns of use of disposable ENDS through surveying college students. METHODS/STUDY POPULATION: Disposable ENDS are all-in-one devices with pre-filled nicotine liquid and a built-in battery. Recent data shows increased sales as users, including youth, are switching from pod-based to disposable ENDS. Gaps were identified via a literature review of current survey data revealing unknown information about disposable ENDS. Based on these data gaps, an anonymous survey was developed to gain insight into youth disposable ENDS use. The survey was distributed to college students via social media, university email chains, and flyers with QR codes. Responses were analyzed to identify trends and correlations in disposable ENDS use among college students. The survey was approved by USC IRB, Study ID: UP-22-00023. RESULTS/ANTICIPATED RESULTS: Between March 6 and October 28, 2022, 166 completed survey responses were collected; 158 were students. 80.4% (127/158) of surveys were eligible for analysis with the following criteria: 18-20 years old, under the US legal age to use ENDS. Of respondents aged 18-20, 57.5% (73/127) reported using ENDS at least once. 79.5% (58/73) of underage respondents used disposable ENDS and 72.9% (51/70) reported disposable ENDS as their usual device. 93.0% (53/57) of underage users reported using a flavored product, 56.1% (32/57) reported FlumÂ®as their usual brand, 48.2% (27/56) reported convenience of use as the most attractive aspect of disposable ENDS, and 46.4% (26/56) obtained disposable ENDS from a convenience store. Of all disposable ENDS-using respondents, 98.7% (75/76) used for the first time while under the age of 21. DISCUSSION/SIGNIFICANCE: The survey continues to be open for data collection, with the goal of obtaining additional data. The goal with the additional data will be to create a comprehensive list of identified risk factors influencing underage disposable ENDS use and to suggest specific regulatory and policy reform to better address underage nicotine addiction.

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Examining the Landscape of Clinical Trials Targeting Alcohol or Opioid Use Among Homeless Individuals

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OBJECTIVES/GOALS: To understand the current landscape of clinical trials involving the homeless population by examining opioid or alcohol use disorders and the challenges in clinical trial recruitment. METHODS/STUDY POPULATION: Clinicaltrials.gov was searched with the keywords homeless or unhoused. The search was limited to studies conducted in the United States that were recruiting, not yet recruiting, active and not recruiting, completed, and enrolling. The search findings were further characterized and categorized by the definitions that were used for homelessness. Next, the trials were grouped based on the inclusion of alcohol or opioid use: (A) had no relevant mention, (B) included alcohol or opioid use as a secondary or other outcome measure, or (C) alcohol or opioid were the primary focus of the trial. Lastly, patterns and trends were identified for these trials. RESULTS/ANTICIPATED RESULTS: Out of 161 trials, 77 trials that met search criteria were identified then grouped based on how they classified homelessness: McKinney-Vento (n=5, 6%), DHHS (n=4, 5%), HUD (n=2, 3%), HEARTH Act (n=3, 4%), Custom (trials that specified parameters for homelessness, n=12, 16%), Not Specified (trials that provided no parameters for homelessness, n=26, 34%), and Other/Ambiguous (trials that used enrollment in an independent program as parameters or had unclear parameters, n=25, 32%). Of the 77 clinical trials that targeted homeless populations, 65% did not include alcohol use and 100% did not include opioid use in any outcome measure, 22% included alcohol use in a non-primary outcome measure, and 13% included alcohol use as the primary outcome measure of the study. DISCUSSION/SIGNIFICANCE: The number of clinical trials targeting homeless populations has increased over time, yet there is still no universal definition for classifying an individual as homeless. This lack of harmonization poses a challenge when coupled with the findings that there is a lack of clinical trials targeting opioid or alcohol use disorders.

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Hindering Generic Antiretroviral Treatment Competition for Human Immunodeficiency Virus: Anti-Competitive Agreements and HIV Disease Management Concerns

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OBJECTIVES/GOALS: To understand the implications of minimal HIV generic drug availability on long-term HIV disease management, including anti-competitive agreements and patent strategies that hinder (ART) competition and ART medication safety and efficacy improvement. METHODS/STUDY POPULATION: Individuals living with Human Immunodeficiency Virus (HIV) require sustained ART treatment. Despite excessive ART costs, the treatments use active ingredients known to be toxic, causing bone and renal impairments. A review of pharmaceutical legal cases examined the role of strategic patenting–product hopping–and anti-competitive agreements, which prevent generic competition and contribute to minimal ART improvement. A literature review explored the long-term safety effects of ART medications on HIV patients and disease management. A cost analysis of HIV disease management assessed the implications of using treatments with known toxins and their contribution to comorbidities and their effect on the cost of overall HIV disease management. RESULTS/ANTICIPATED RESULTS: Ongoing lawsuits of major ART medication manufacturers demonstrate the intentional agreements made to hinder generic competition, which is an inherently anti-competitive strategy. Thus, prices for ART medications remained high, causing treatment costs to be a significant barrier to treatment access. Further, the entry of a new ART, Tenofovir Alafenamide Fumarate (TAF), was delayed despite knowing the key active ingredient in Tenofovir Disoproxil Fumarate (TDF) was toxic to patients long-term. As a result, patients were more likely to experience comorbidities, significantly increasing the cost of HIV care. The average cost of HIV care without comorbidities is $30,312. However, HIV care is $46,000 for two comorbidities and about $219,000 for people with 11 or more. DISCUSSION/SIGNIFICANCE: Abuse of patent rights prevents more effective HIV medication and generic option development. Thus, HIV disease

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