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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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management is inhibited. The only method of HIV disease management is patient adherence to ARTs. Patients taking less effective medications increase the development of comorbidities from toxic treatments, magnifying the cost of HIV care.

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Quantitative Analysis of FDA Warning Letters Related to the Use of Social Media Sites in Product Misbranding for the Treatment, Prevention, or Diagnosis of COVID-19

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OBJECTIVES/GOALS: Food and Drug Administration (FDA) warning letters regarding misbranding of products intended to treat, prevent, or diagnose COVID-19 were used as a proxy for assessing misinformation on social media. The FDA database of Warning Letters was used to identify the largest misinformation contributor. METHODS/STUDY POPULATION: On November 9, 2022, the full dataset of warning letters dating back to January 1, 2018 was extracted from the FDA website. Separate datasets were also extracted using the search terms: Facebook', Twitter', YouTube', and Instagram'. The data entries were organized by issuing office and subject. The subjects were then filtered to only include letters related to misbranding of products for COVID-19. Letters regarding medical devices, manufacturing practices, and adulterated products were excluded from the analysis. Cumulative totals were collected for the number of letters issued for each search term. These totals were stratified by year and scaled by platform size for relative comparison. RESULTS/ANTICIPATED RESULTS: The FDA's Center for Drug Evaluation and Research issued the most letters related to misbranding of COVID-19 products, 153 out of the 2798 entries in the complete dataset. Analysis of the datasets by search term show: 53, 18, 24, and 17 letters were related to Facebook, Twitter, YouTube, and Instagram respectively. Forty-one letters were related to other non-social media sources. Facebook had the most letters issued, however when scaled to account for the size of each respective platform's approximate user base, Twitter had the largest proportional amount of misinformation regarding agents for the management of COVID-19, followed by Facebook, then Instagram. Most letters were issued in 2020. DISCUSSION/SIGNIFICANCE: In light of COVID-19, many social media sites adopted policies to limit inaccurate information. The success of these efforts have been variable. Although Facebook is the largest absolute contributor assessed, greater attention should be given to the policies of other platforms utilized by the industry.

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Regulations and Marketing of Energy Drinks in the United States: A Survey of University Student Beliefs about Caffeine Consumption

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OBJECTIVES/GOALS: To understand how energy drinks are marketed and regulated and the effects of these policies on adolescent consumption and perceptions of the product. METHODS/STUDY POPULATION: A review of research studies using the PubMed database (PubMed.gov); clinical trials (clinicaltrials.gov); FDA Recall, Market Withdrawals, and Safety Alerts (FDA.gov); and emergency department (ED) visits from reports from the Drug Abuse Warning Network (DAWN) were conducted. A survey is being designed and will be sent to undergraduate and graduate university students through advertised QR codes and university email chains sent out to student organizations and courses. The survey will determine the percentage of respondents who consume caffeine, the frequency in which individuals consume caffeine, and reasons for consuming caffeine. The survey also seeks to understand perceptions and thoughts on energy drinks and caffeine regulation and consumption. RESULTS/ANTICIPATED RESULTS: From January 1st, 2000, to August 5th, 2022, 112 research studies investigated the physiological impact of energy drinks on adolescents, and 13 clinical trials from the age group of 0-17 were conducted. No FDA recalls have been observed for energy drinks or the top 4 brands within the US (by sales; Red Bull, Monster, Bang Energy, Rockstar), though some recalls regarding container manufacturing were made outside the US. ED visits from energy drinks doubled from 2007 to 2011 with 1/10 of them resulting in hospitalization. 58% of the total ED visits were exclusively related to energy drinks. It is anticipated that survey results will indicate trends of frequent caffeine/energy drink consumption among college students for studying, but students will not have a clear understanding of recommended caffeine intake. DISCUSSION/SIGNIFICANCE: Due to the lack of regulations and studies surrounding energy drinks, the dangers (as seen from ER visits) to public health are concerning. Regulatory agencies should invest in developing new protocols or regulations regarding the content of energy drinks as well as find ways to monitor the marketing strategies more closely behind them.

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Researcher Perceived Barriers in Translational Research

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OBJECTIVES/GOALS: To identify, categorize, and streamline the wide range of commonly encountered barriers in translational research that prevent studies from progressing along the translational research spectrum through a comprehensive needs assessment survey. Results will be utilized to institute potential solutions to overcome these identified barriers. METHODS/STUDY POPULATION: The comprehensive survey consisted of three sections, Demographics and Background, Self-Reporting of Barriers, and Comments and Feedback. An extensive literature review was conducted to develop and compile questions and barrier categories for the survey. The survey content was derived from primary literature sources and supplemented with the NCATS Translational Science course material. The target population for the survey included all researchers engaged in translational research at the NJ ACTS CTSA hub. The hub includes Rutgers, Princeton, and NJIT and all of their affiliated institutions and partnered healthcare systems, such as Robert Wood Johnson Barnabas Health and University Hospital. Results will be analyzed according to the type of research conducted and stage of translation research (T0-T4). RESULTS/ANTICIPATED RESULTS: Examples of the survey barrier categories being analyzed include Regulatory/IRB, Funding, Collaborations and Networking, and Training. Initial analysis (N=106) consisted of these top barriers in the NJ ACTS CTSA hub: obtaining timely IRB approval, inadequate staffing for the research team, and lack of holistic institutional support. After

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