residents of the state of Michigan or the local county surrounding MM (Washtenaw County), using US Census tract data to provide context for these findings. RESULTS/ANTICIPATED RESULTS: MM patients who received EA treatments were more likely to come from neighborhoods that showed markers of high SES compared to residents of the state of Michigan but not Washtenaw County. This includes the proportion of persons living in poverty (12.5% EA / 13.4% Michigan / 12.4% Washtenaw) and education in the form of a bachelor's degree or higher (32.2% / 30.6% / 57.2%). This varied by the disease being treated. Oncology patients were more likely to be from areas with less poverty and more education (12.4% / 76.8%) than the EA average. EA patients being treated for infectious diseases were from areas with more poverty and less education (13.5% / 26.7%). DISCUSSION/SIGNIFICANCE: Patients treated at Michigan Medicine using treatments obtained through the EA pathway came from areas that were, on average, more affluent than residents of the state of Michigan as a whole. This finding warrants more research to ensure equitable access to these therapies for patients in disadvantaged neighborhoods.

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Examining Participant Representation in Atopic Dermatitis Clinical Trials from 2011-2022

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OBJECTIVES/GOALS: This study seeks to comprehensively evaluate the extent to which participants in clinical trials (CT) for Atopic Dermatitis (AD) accurately mirror the demographics and characteristics of the broader AD-affected populations. We will achieve this objective by analyzing data from AD CTs spanning the years 2011 to 2022. METHODS/STUDY POPULATION: We examined completed trials for 10 FDA approved treatments for AD, utilizing data sourced fromclinicaltrials.gov [http://clinicaltrials.gov]. In light of the increased number of AD clinical trials over the past decade, we tailored our search parameters to encompass all trials related to approved treatments from 2011-2022. To assess the characteristics of the participant population in these trials, information including inclusion and exclusion criteria, age, location, sex, and disease severity were collected for each trial. Furthermore, race and ethnicity data were also extracted and analyzed. Additionally, comparisons were drawn between trials completed before and after April 2017, when the FDA began requiring that researchers publish race and ethnicity data toclinicaltrials.gov [http://clinicaltrials.gov]. RESULTS/ANTICIPATED RESULTS: Across 67 CTs examined, 45% of trials were restricted to adult patients, 28% were restricted to pediatric patients, and 27% included both. 77% of CTs occurred in urban settings and 23% occurred in rural settings according to the The Economic Research Service definition. 36% of CTs included mild-to-moderate AD patients, and 64% of CTs included moderate-to-severe AD patients. Race distribution of CTs revealed 67% White, 14% Black/African American, 16% Asian, and 3% others. 13% of participants identified as Hispanic or Latino. With further analysis, we will determine whether there is a difference in ethnic distribution between trials completed before and after April 2017, when the FDA started requiring race/ethnicity data to be submitted. DISCUSSION/SIGNIFICANCE: The findings highlight a significant concern in AD CTs: the insufficient representation of Black and Asian populations. The findings emphasize the need for a more inclusive selection process that accurately reflects the diversity of patients. Failing to do so could undermine the assessment of treatment effectiveness in such populations.

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A Comparison of Regulatory Mechanisms for the Approval of Herbal Medicines

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OBJECTIVES/GOALS: To compare the herbal medicine (HM) programs of the U.S. to those of different countries–including the European Union, South Korea, China, and India–and to examine each regulatory body's process for obtaining market approval for HM drugs. METHODS/STUDY POPULATION: The European Union, South Korea, China, and India's respective HM regulatory programs were examined and compared to the U.S. FDA's HM process. These specific regulatory bodies were chosen based on the country's long history with HM and/or the robustness of their existing HM review processes. International HM programs were researched using official government websites and journals published by independent, external research institutions that were accessed via USC's library services. Data regarding the efficacy of HM policies such as HM IND approval rates, number of marketed HM drugs, and establishment of unique HM sectors will be collected. RESULTS/ANTICIPATED RESULTS: Investigational New Drug (INDs) applications regarding HM from each country will be categorized and displayed according to their approval status in order to provide insight on a HM program's efficiency. Results also included a table displaying common challenges for approval for HM drugs across federal regulatory bodies. If applicable, effective solutions implemented to address some of these obstacles that proved to be effective will also be displayed in the form of a table. DISCUSSION/SIGNIFICANCE: Tables displaying the collective flaws of international HM programs and the resulting regulatory solutions can provide clearer guidance for companies seeking to submit HM INDs and for the U.S. FDA seeking to develop improved HM regulations.

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A Multi-Institutional Look at Single-Patient Expanded Access Submissions

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OBJECTIVES/GOALS: Physicians can request the clinical use of investigational products for their patients through an FDA pathway called Expanded Access (EA). Most evaluations of EA focus on the FDA submission only. We sought to evaluate these requests through

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