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## **FDA's Focus Groups for the Project "Educating Groups Influencing Generic Drug Use" Summary of Focus Groups Being Conducted**

FDA's Center for Drug Evaluation and Research, Office of Generic Drugs needs to conduct focus groups to help understand roles of key groups and the extent of their influence on generic drug use in order to provide additional and effective educational outreach to meet their informational needs. To this end, we are studying key groups, determining the extent of their influence and informational needs regarding generic drugs overall and by specific drug class, and developing generic drug educational materials using a mixed-methods approach including systematic reviews of clinical and observational studies, robust empirical analyses of publicly available datasets and surveys, and qualitative key informant interviews and focus groups.

**What was the problem to be investigated?** Evidence shows that generic drug use is largely impacted by certain key groups' behaviors and perceptions towards generic drugs. These key groups include patients/caregivers, prescribers, pharmacists, insurance formulary managers, state health policy makers, and large purchasers of drugs. While believed to be influential, the extent of each group's influence is heterogeneous and dependent on factors such as experiences and perceptions with generic drugs and the changing costs of certain drugs or therapeutic classes. Other key groups or factors might also influence generic drug use. It is important for consumers, health care providers, researchers, policy makers and other stakeholders to understand the drivers of generic drug prescribing and use, in order to design policy or programs that promote the "triple" aim of better care, smarter spending, and healthier people. Thus, effective educational efforts to target all types of barriers that may limit generic drug use are a critical need.

**The method used to form the focus groups.** An Auburn University research team recruits prescribers, pharmacists, patients/caregivers, formulary managers, large purchasers of drugs, and policymakers from Auburn University and Edward Via College of Osteopathic Medicine (VCOM) students, faculty, and staff. Participant eligibility differs by group; participants meeting the eligibility requirements are asked if they wish to participate in the study provided they are able to during the designated date and time yet to be determined. Participants who are available and wish to participate in the focus group receive a reminder via email of their scheduled focus group two days prior to their scheduled discussion date and time.

**Burden imposed.** A burden of approximately 24 hours in total is estimated based on 1-hour focus group discussions for a maximum of 24 participants in 4 focus groups. The maximum anticipated total number of participants is 24, and the minimum anticipated total number of participants is 12 (3 participants in each group for a total of 4 focus groups).