Sample Patient Informed Consent Statement

Optum
Informed Consent Statement
"Patient Perspectives on Generic Drug Appearances"

You are being asked to participate in a research study focused on patients' perspectives on the appearance of prescription medications. The goal of this research study is to help the Food and Drug Administration understand patients' views on the appearance of generic drugs to guide future programs aimed to promote positive outcomes in patients.

INFORMATION
You are being asked to take part in this study because you are a UnitedHealth Group health plan enrollee. You were randomly chosen to be asked to participate in this survey study from a large list of adults who have received a prescription for the selected generic drug(s) in the last few months.

About 2,000 participants will be invited to complete this survey. The survey collection period will last for approximately 10 weeks. This is a one-time survey. It should take no more than 20 minutes to complete.

If you agree to participate, please complete the survey that has been included in this booklet on paper ***or*** online. The survey includes questions about your experiences with receiving a prescription drug during a routine refill that has changed in appearance, questions about whether your pharmacist notified you of the change, and general questions about you. You have been provided with a postage-paid envelope for returning this survey booklet by mail to ANA Research (ANA), or you may complete the survey online by using the web address and password provided to you in the survey invitation letter. As a part of this study, the research staff will review any submitted health care and pharmacy claims (which contain your medical information) related to this survey study during the study period, and up to twelve (12) months prior to your participation.

BENEFITS
There are no direct benefits to you from participating in this survey study.

RISKS
There are no direct risks to you from participating in this survey study.

COMPENSATION
You have already received $5.00 with your invitation letter, and you will receive a $20.00 Amazon gift card once we receive your completed survey. In order to qualify for the payment, we must receive your completed survey either by mail or online by the date indicated in the attached invitation letter.

CONFIDENTIALITY
Individual subjects will not be identifiable. Please do not write your name or other identifiable piece of information anywhere on the survey.

CONTACT
If you have any questions about this study, you can contact Laura Pierce, Optum Epidemiology Research Associate, toll-free at 1-855-272-2876.

Questions regarding your health should be directed to your doctor. If you experience any illness, health problems, or concerns, please contact your doctor directly. If you have questions about your rights as a research subject, or other concerns about the research, you can contact New England Institutional Review Board (NEIRB), toll-free at 1-800-232-9570.

PARTICIPATION
By mailing the attached survey or filling out the survey online, you are agreeing to participate in this study. Your participation in this study is completely voluntary. You may stop your participation in this study at any time. Your decision will not result in any penalty or loss of benefits to which you are entitled. You may stop your participation at any time by informing Laura Pierce that you wish to withdraw from this study.