FDA DOCUMENTATION FOR THE GENERIC CLEARANCE, "DATA TO SUPPORT SOCIAL AND BEHAVIORAL RESEARCH" (0910-0847)

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TITLE OF INFORMATION COLLECTION: Stated Preference Survey of Willingness to Pay for Prescription Medication Information

DESCRIPTION OF THIS SPECIFIC COLLECTION

1. **Statement of need:**
   When patients fill a prescription at a pharmacy, they are usually given written information about their medication. FDA has long recognized the importance of providing patients with written information about their medications. Studies have suggested that such information may help patients use prescription drug products safely and effectively and may potentially reduce preventable adverse drug reactions and improve health outcomes. However, the information that patients currently receive with their medications is often lacking in key measures. The information is frequently duplicative, incomplete, conflicting, or difficult to read and understand and is not sufficient to meet the needs of patients. In addition, different pharmacies or pharmacy chains provide this information in different formats.

   Research has evaluated patient preferences for the information they receive with their prescription medication. This research has found that patients prefer to receive their information in a standardized format over the various unstandardized formats that are currently provided. However, there is limited evidence on how much patients would value prescription medication information in a standardized format. It is also difficult to conduct long-term outcome studies on behavioral changes attributable to standardized formatting of such information. The results from this survey will help to fill that gap by providing quantitative data on patient preferences for information.

2. **Intended use of information:**
   In order to estimate the value to patients of standardizing the written information they receive with their medications, FDA has developed this stated preference survey to be administered online using a web-based platform. This survey will elicit patients' willingness to pay (WTP) for Prescription Medication Information in a standardized format. This data will be used to better understand patient preferences for the information they receive with their medications and to estimate the consumer surplus they gain from that information.

3. **Description of respondents:**
   The survey will be administered, on a voluntary basis, to a nationally representative sample of adults in the U.S., covering both genders and all geographic areas, age groups, income levels, and levels of educational attainment.

   We have contracted with Ipsos Public Affairs, LLC (Ipsos) to administer the survey to a nationally representative sample of members of their KnowledgePanel. KnowledgePanel is the largest online panel that is representative of the U.S. population, which is

constructed using probability-based sampling techniques by relying on the latest version of the Delivery Sequence File from the USPS.

4. **Date(s) to be Conducted:**
   September 1, 2019 – December 31, 2019

5. **How the Information is being collected:**
   We have contracted with Ipsos Public Affairs, LLC (Ipsos) to administer the survey online using a web-based platform. The survey will be administered in two phases: (1) a survey pretest and (2) main data collection.

   In the pretest, Ipsos will conduct 30 online interviews using the survey instruments. The pretest will be used to verify that the survey instrument is functioning correctly and that the respondents understand the question wording and response categories. It will also be used to estimate and confirm the survey incidence/eligibility rate, to estimate the consent or cooperation rate, and to estimate the median survey length as well.

   During the main data collection phase, Ipsos will administer the survey online to a nationally representative sample of their panel members from KnowledgePanel.

6. **Confidentiality of Respondents:**
   Ipsos has strict procedures and privacy policies in place to ensure the confidentiality and anonymity of all survey respondents.

7. **Amount and justification for any proposed incentive**
   To maximize cooperation rates for this survey, Ipsos will provide respondents with a $1 incentive, using the KnowledgePanel points system. We believe it is necessary to provide a modest financial incentive to respondents in order to maximize the cooperation rate and ensure careful completion of all questions on the survey. By maximizing the survey cooperation rate, we believe the possibility of selection bias affecting the quality of results will be reduced.

8. **Questions of a Sensitive Nature**
   None

9. **Description of Statistical Methods**
   Ipsos will select a maximum sample of about 10,000 panel members from KnowledgePanel to achieve a minimum survey cooperation rate of at least 50% (defined as AAPOR RR5 in AAPOR standard definitions). The sample will be selected using a proprietary probability proportion to size (PPS) sampling process that yields a probability-based nationally representative set of American households. Briefly, this methodology starts by weighting the entire KP to the benchmarks secured from the latest March supplement of the Current Population Survey (CPS) along several dimensions. This way, the weighted distribution of KP will match that of the US adults – even with respect to the above mentioned few dimensions where minor misalignments may result from differential attrition rates. Using these panel weights as the measure of size (MOS) for each panel member, the PPS procedure is used to select study specific samples that match the U.S. adult population on key geodemographic characteristics such as gender,

age, race, ethnicity, educational attainment, household income, Census region, and metro status.

To gauge WTP for standardized prescription medication information, we will administer two versions of the survey instrument, with half of the respondents receiving each version. The first version is a referendum format with a Split Ballot procedure using two binary WTP questions. We have already piloted this survey instrument using a panel of FDA employees from the Agency's Internal Message Testing network. This protocol randomly assigns respondents to one of the nine starting bid values. If a respondent accepts the first bid amount, the respondent is then asked to accept or reject a second, larger big. Conversely, if a respondent rejects the initial bid amount, a second, lower bid value will be presented. The first and second bid values are shown in the table below.

BID VALUES

First Bid	Second Bid if Respondent Rejects First Bid	Second Bid if Respondent Accepts First Bid
$1.00	50¢	$2.00
$2.00	$1.00	$4.00
$4.00	$2.00	$8.00
$8.00	$4.00	$16.00
$16.00	$8.00	$32.00
$20.00	$10.00	$40.00
$30.00	$15.00	$60.00
$40.00	$20.00	$80.00
$50.00	$25.00	$100.00

The second version of the survey instrument elicits WTP using an open-ended valuation question. We developed this version based on our experience piloting the referendum format and to address some of the common shortcomings associated with it, such as anchoring effects, starting point bias, and yea-saying. Although open-ended valuation surveys are not without their own drawbacks, we believe that by administering the survey in both formats, we will be better able to address the various sources of biases that may arise.

Once the study sample has been selected and fielded, and all survey data have been edited and made final, analysis weights will be computed to accompany the resulting survey data. Virtually all survey data are weighted before they can be used to produce reliable estimates of population parameters. While reflecting the selection probabilities of sampled units, weighting also attempts to compensate for practical limitations of a sample survey, such as differential nonresponse and undercoverage. Furthermore, by taking advantage of auxiliary information about the target population, weighting can improve the external validity of the resulting survey estimates.

Our weighting process for this survey will include several steps. In the first step, design or base weights will be computed to reflect selection probabilities for all survey assignees. In the second step, base weights will be adjusted for nonresponse, while in the third step nonresponse-adjusted weights will be ratio adjusted (raked) to the

geodemographic characteristic distributions of the US adults. In the final step, calculated weights will be examined to identify and, if necessary, trim outliers at the extreme upper and lower tails of the weight distribution to avoid excessive variability in the weighted survey estimates.

The needed population benchmark distributions for weighting will be obtained from the latest Current Population Survey (CPS). Should survey data for any demographic questions that will be used for weighting – such as race, age, and education – include missing values, all such missing values will be imputed before construction of the survey weights can commence. We will use a *hot-deck* procedure to identify eligible donors to fill the missing data (http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3130338).

BURDEN HOUR COMPUTATION *(Number of responses (X) estimated response or participation time in minutes (/60) = annual burden hours):*

Type/Category of Respondent	No. of Respondents	Participation Time (minutes)	Burden (hours)
Individuals	5,030	10	838

REQUESTED APPROVAL DATE: September 1, 2019

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