15 Year Review (2006-2020) of Patient-Reported Outcomes Labeling for Oncology Products Approved by the Center of Drug Evaluation and Research (CDER)

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Introduction: While traditional endpoints for oncology clinical trials focus on objective assessments such as tumor response and survival, patient-reported outcomes (PROs) reflect the patient's perspective on their health. Although the Food and Drug Administration (FDA) published guidance encouraging PRO in oncology studies, PRO language in product labeling remains scarce. The purpose of this review is to determine if the rate of PRO inclusion in oncology labeling has meaningfully changed from 2006 to 2020. Additionally, the types of sponsors who obtained PRO label content were ascertained.

Methods: PRO label data for oncology product approvals between 2006-2014 were obtained from prior publications (Gnansakthy et al., 2012, 2016). Data for 2015-2020 approvals were obtained utilizing the same methodology. Monthly FDA Drug Approval Reports were obtained and searched for initial oncology product approvals. The labels and FDA approval summaries for these products were then reviewed for PRO inclusion. Sponsor disposition was assessed for labels containing PRO.

Results: Of 147 oncology approvals between 2006-2020, 8 labels contained PRO. PRO data varied and included measurements of pain, symptoms, and treatment preference. With one exception, sponsors who achieved PRO label content had > 10,000 employees and > 5 marketed oncology products. Sponsors with PRO product labeling included Genentech, Celegene/BMS, Bayer, Janssen, Incyte Corporation, and Pfizer.

Discussion: The rate of PRO inclusion in product labeling has not meaningfully increased over 15 years. Successful sponsors were mostly large companies with extensive oncology pipelines. Sponsor experience in oncology may be a factor in PRO development, utilization, and label inclusion.