# Updating Labels for Generic Oncology Drugs

Hosted by the National Cancer Policy Forum
In Collaboration with the Forum on Drug Discovery, Development, and Translation

Keck Center of the National Academies
Room 100
500 Fifth Street, NW
Washington, DC 20001

**AGENDA**

<table>
<thead>
<tr>
<th>Time</th>
<th>Event</th>
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<tbody>
<tr>
<td>7:30 am</td>
<td>Registration and Breakfast</td>
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| 8:00 am | **Welcome and Opening Remarks**
          Harold L. Moses, Vanderbilt-Ingram Comprehensive Cancer Center
          Planning Committee Chair
          Richard Pazdur, Food and Drug Administration                   |
| 8:15 am | **Session 1: Background and Overview of the Goals of the Meeting**
          Moderator: Andy Bindman, University of California, San Francisco
          FDA overview of Project Renewal and regulatory requirements for
          labeling updates (15 mins)
          • Paul Kluetz, Food and Drug Administration
          Evidence review processes for clinical practice guidelines/compendia
          in oncology: lessons learned and how they could inform evidence
          review process for updating labeling (15 mins)
          • Ethan Basch, University of North Carolina, Chapel Hill
          Case examples of how outdated labeling affects clinician prescribing
          and patient care (15 mins)
          • Donald Harvey, Emory University
          Panel Discussion
          Include speakers and
          Lia Gore, University of Colorado & Children’s Hospital Colorado
          Rajeshwari Sridhara, Food and Drug Administration |
<table>
<thead>
<tr>
<th>Time</th>
<th>Session Description</th>
<th>Objectives</th>
<th>Notes</th>
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<tbody>
<tr>
<td>9:15 am</td>
<td><strong>Introduction to Small Group Discussions</strong></td>
<td>Overview of the format and plans for small group discussions</td>
<td>Identify moderators/note takers for each table</td>
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<tr>
<td>9:30 am</td>
<td><strong>Session 2: Sources of Information</strong></td>
<td>Objectives:</td>
<td>• In small groups, discuss what sources of information could be used to update labels for generic oncology drugs, as well as the challenges and considerations that should be considered when using different information sources (e.g., clinical trials data, meta-analyses, real world evidence).</td>
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<td>• Reconvene at 10:30 am to report out main points for broader discussion.</td>
<td>o S. Gail Eckhardt will moderate the report back discussion.</td>
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<td>11:30 am</td>
<td>Lunch</td>
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<td>12:15 pm</td>
<td><strong>Session 3: Evidentiary Standards for Information Sources</strong></td>
<td>Objectives:</td>
<td>• In small groups, discuss what the evidentiary standards should be for different sources of information discussed in the prior session.</td>
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<td>• Reconvene at 1:15 pm to report out main points for broader discussion.</td>
<td>o Richard L. Schilsky will moderate the report back discussion.</td>
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<td>2:15 pm</td>
<td>Break</td>
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<td>2:30 pm</td>
<td><strong>Session 4: Evidence Considerations for Select Populations</strong></td>
<td>Objectives:</td>
<td>• In small groups, discuss how the strength of evidence and sources of evidence may differ depending on the population being considered (e.g., pediatric populations, patients with comorbidities, those with rare cancers, biomarker-defined population subsets).</td>
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- **Reconvene at 3:30 pm** to report out main points for broader discussion.
  - Katherine Warren will moderate the report back discussion.

| 4:30 pm | Session 5: Advancing Progress on Updating Generic Oncology Drug Labeling  
Moderator: Harold L. Moses, Vanderbilt-Ingram Comprehensive Cancer Center Planning Committee Chair  
Objectives:  
- Review key messages from the meeting discussions, including identifying potential next steps, promising areas for future action, and opportunities for collaboration to revise outdated labeling for generic oncology drugs.  
Panelists (each with 5 minutes for opening remarks, followed by open discussion among the meeting participants)  
- Andy Bindman, University of California, San Francisco  
- S. Gail Eckhardt, The University of Texas at Austin  
- Susan Halabi, Duke University School of Medicine  
- R. Donald Harvey, Emory University  
- Ishmael Jaiyesimi, William Beaumont Hospital  
- Rebecca Miksad, Flatiron Health  
- Richard L. Schilsky, American Society of Clinical Oncology  
- Steven Sun, Janssen Inc.  
- Josephine M. Torrente, Hyman, Phelps & McNamara, P.C.  
- Katherine Warren, National Cancer Institute |

| 6:00 pm | Adjourn |