The Denali Oncology Group (DOG) and the American Society of Clinical Oncology (ASCO) strongly support increasing access to investigational new treatment options for patients with cancer. We are concerned, however, that the Alaska Right to Try legislation, HB 43, lacks adequate patient protections and does not meaningfully remove the major barriers patients face in accessing investigational drugs outside of clinical trials. We therefore oppose HB 43.

The DOG, an organization of oncologists and other health care professionals, is the Alaska Affiliate of ASCO. ASCO is the national organization representing nearly 45,000 physicians and other healthcare professionals specializing in cancer treatment, diagnosis, and prevention.

The federal Food and Drug Administration (FDA) offers access to investigational drugs outside of clinical trials through their Expanded Access program, also known as “compassionate use” — for patients with serious diseases or conditions. The FDA streamlined the previously burdensome approval form in 2016 and approved approximately 99.5% of expanded access requests with a median approval time of four days for non-emergency cases.

Additionally, the 21st Century Cures Act (Cures Act) enacted by Congress in late 2016 further simplified access to investigational drugs by requiring drug manufacturers to make information about their expanded access policies and processes readily available to patients and providers.

In response to the Cures Act, the nonprofit Reagan-Udall Foundation for the FDA released an online resource called the Expanded Access Navigator in 2017. The Navigator provides manufacturers’ information and guides patients and physicians through the expanded access process, beginning with assessing whether all approved therapeutic options for patients with serious or life-threatening conditions are exhausted. ASCO was one of several organizations to help develop the Navigator.

ASCO and DOG support policy initiatives that focus on increasing transparency among pharmaceutical manufacturers' expanded access policies while ensuring that existing expanded access programs are timely and efficient for patients and their physicians.

We appreciate Alaska’s efforts to support patients but are concerned that, while well intentioned, HB 43 will not achieve improve patient access for the following reasons:

- It does not offer an independent review of the potential safety and efficacy of investigational drugs, which is critical for patient safety. Under the Food and Drug Administration’s (FDA) current expanded access program, it conducts a prompt review of the available data and makes
an independent assessment of the risks and potential benefits of the proposed treatment on behalf of the patient.

- It does not include an enforcement mechanism to provide access for the patients and it does not require or compel drug manufacturers to provide investigational products. As such, it does not remove a frequent barrier to patient access.
- It does not help the patient determine a manufacturer's willingness to provide the investigational drug.
- It places no legal obligations on insurers to pay for the routine care costs associated with delivery of treatment, particularly in the case of complications caused by these drugs— unlike coverage requirements that exist for patients who participate in clinical trials. Thus, the patient may be burdened by additional and unexpected costs associated with access provided by this bill.

If you have any questions or would like assistance on this issue, please contact Katherine Flannigan at Katherine.flannigan@asco.org.

Sincerely,

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