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June 1, 2015

The Honorable Laurie Monnes Anderson
Chair, Senate Health Care Committee
State Capitol
Salem, Oregon 97301

RE: House Bill 2300

Dear Senator Monnes Anderson and members of the committee:

Providence Health & Services is a research leader in Oregon. Our centers of excellence, such as cancer and heart, participate in a variety of clinical trials to find new ways to improve patient care and find cures to deadly diseases. We recognize the importance of new drugs and devices and fully support efforts to improve patient access to clinical trials, as well as access to experimental drugs outside a clinical trial through the Compassionate Use category for these drugs. This compassionate use is based on research suggesting there may be benefit and is done with the oversight by the FDA and our own Institutional Review Board, of which I am a member to assure patient safety. From 2010 to 2014, fully 99.5% of all compassionate expanded use requests were approved by the FDA for patients approaching the end of life, and in February of this year the FDA announced further reforms to streamline this process. Providence fully supports the use of non approved drugs in this setting.

House Bill 2300, however, raises numerous clinical and ethical concerns, including:

- Drugs/Devices that have only passed Phase I clinical trials have little to no data as to clinical efficacy or appropriateness. Phase I trials have as their purpose finding safe dosing so that efficacy trials can be conducted. The bar we believe is too low for patients to be offered safely with reasonable hope of benefit. We have an ethical duty of nonmaleficence to not put patients at risk for harm without reasonable hope of benefit.

- Patients and their families are in a vulnerable state when they hear that they are running out of options to manage their disease and may, in desperation, find themselves willing to consent to interventions for which there is insufficient evidence of benefit to ethically offer it to them. Patient autonomy in making choices is not advanced in the context of lacking information and emotional distress.

- This bill would apply to children (15-18). This puts tremendous pressure on parents who, of course, want to do all they can for their children. We believe the current compassionate use process provides better clinical and emotional safety for all involved. There are some choices parents should not have to make relative to quality of time or potentially risky treatments to extend time.

- The bill puts clinicians who must practice with integrity as professionals in the awkward and difficult position of making a judgment call themselves which currently is made by experts who, with much more evidence, can better assess the unapproved, extended use of some drugs for that particular patient. This could also damage the therapeutic relationship between the clinician and patient when the clinician truly does not believe the use of the unapproved drug will be of benefit or wants to rely on the current review proves. Disrupting these relationships at this vulnerable time serves no one's good.

- Financial concerns are real – these treatments, and adverse events that may be related, can be extremely expensive. Because the drugs will only have completed Phase I trials, it will be difficult to know what side-effects are caused by the drug and it likely will happen that a presumption will be made that it is the drug causing a problem. Adverse events can be difficult to evaluate. The patient, and their family, is solely responsible for the costs under 2300A – this could easily lead to medical bankruptcy that can be avoided by retaining the current FDA compassionate use process.

No one ever likes to believe that there's nothing else that can be done to treat a disease and that the time has come to begin to manage one's final days, and HB 2300A appears to provide another avenue to keep hope alive. IT does so, however, without the proven safeguards to assure patient safety, financial stability and clinically reasonable options that are currently in place, and the evidence makes clear works very well. People who are vulnerable need protection from unrealistic or unsafe options. They are facing enough difficult decisions.

The real justice issue of access to experimental drugs is not for the terminally ill, but for the poor and minority communities who rarely get into approved clinical trials. We should allow the new FDA process for compassionate use time to prove itself before opening the door to more nonscientific use of experimental drugs.

Sincerely,

Fr. John Tuohey
Senior Director, Center for Ethics
Providence Health & Services