OREGON LIABILITY REFORM COALITION

TO: Chair Prusak, Members of the House Health Care Committee
FROM: Fawn Barrie, Oregon Liability Reform Coalition
RE: SB 764 Opposition

The Oregon Liability Reform Coalition represents businesses and associations across a broad array of industries that share the goal of limiting the expansion of lawsuits. We urge opposition to SB 764 because it not only expands liability for pharmaceutical manufacturers but also establishes concerning provisions that warp the burden of proof requirements in civil cases and includes excessive civil penalties. SB 764 includes an uncertain statute of limitations provision and creates a statutory obligation for the courts dictating what the court can and cannot presume in a case. The language in this bill is broad, extremely confusing and is certain to be litigated just as a similar version has been in California. Finally, there is no fiscal recognition by the AG of the potential costs to pursue litigation envisioned in this bill or to defend the state against legal challenges to the legislation.

When a generic manufacturer decides to seek entry to the market prior to the expiration of patents on brand-name drugs, they do so with the knowledge and expectation they will be sued for patent infringement by the brand-name drug company to protect their existing patent. Patent litigation is lengthy, costly and extremely complex. If a suit is filed, the FDA places a 30-month stay on approval of the generic application which is the approximate duration of a patent infringement suit. The strength or weakness of the patents determine whether or not infringement cases are successful, and generic manufacturers must consider critical patent and liability issues in deciding whether or not to even pursue approval of a generic during a patent exclusivity period. Given the costs and potential uncertainty of patent litigation, brand-name and generic companies sometimes settle their patent litigation before a final court decision. This can actually speed up the process of getting generics to market, not delay them, especially given the risk the patent will be upheld. SB 764 will only add to the considerations generics companies weigh about pursuing approval of a generic when a patent is in effect. If Oregon passes SB 764, these companies will now face two additional, separate lawsuits in two different states where they will be required to defend themselves with a presumption that their settlement is anticompetitive and with a minimum of $30 million in litigation exposure on the line because of combined civil penalties. That doesn't include the cost of defending against the suit or "any other remedies available under other law" as stated in SB 764.

As you consider SB 764, I urge you to consider one important question – what is the goal of this legislation? Whether we like AB 824 in California or not, the fact is it remains in effect and allows the California AG to sue in California any company that enters into a drug patent settlement agreement, regardless of location of the company or jurisdiction of the patent litigation. Do we believe Oregon is better positioned than California to pursue these types of lawsuits? What is the goal of allowing the Oregon AG to file lawsuits we can assume will already be filed in California? What happens if other states pursue similar legislation? The approach in SB 764, especially when coupled with AB 824 or similar laws other states may adopt in the future, is certain to lead to unnecessary confusion and uncertainty. This litigation approach has the potential to have a chilling effect on generics companies seeking to speed generic drugs to market by filing applications for patented drugs or entering into agreements that ultimately allow generic drugs to come to market before the end of a patent.

As you have heard, the FTC already receives a copy of settlements entered into by a generic and brand manufacturer based on a 2013 Supreme Court decision that prohibited pay for delay. In that regard, it's important to note that many of the figures cited by proponents are based on an FTC report from 2010, before many of the current requirements went into effect. The threat of the FTC pursuing a case impacted "pay for delay" settlements with the FTC stating in 2019, "The FY 2016 report also indicates that pharmaceutical companies are not only abandoning past practices likely to lead to antitrust liability, but also increasingly using provisions that have received a nod of acceptance by the courts, legislators and/or enforcement agencies." In their most recent report on patent settlements the FTC said, "Despite the high number of settlements, those that include the types of reverse payments that are likely to be anticompetitive

remain very low. In addition, for the first time since FY 2004, no settlement agreement in FY 2017 contains a no-AG (Authorized Generic) commitment."

That's why it's hard to understand the intended goal of SB 764. The bill creates a presumption that any settlement entered into by a generic and brand manufacturer is anticompetitive and violates the statute if the generic manufacturer receives any item of value which is defined as any tangible or intangible item. It further lays out what is not considered an item of value, but the defendant would have to prove there was not an anticompetitive impact.

The entire structure of this proposed statute is confusing. Instead of identifying what constitutes a violation, Subsection (2) of Section 1 establishes what the court must presume when an action is filed including that they must presume a resolution agreement is in violation of the proposed statute. The definitions identify an "Alleged infringer" which is the generic manufacturer and the "Claimant" which is the brand manufacturer. The language, however, never clearly articulates that an alleged infringer or a claimant have violated the statute by entering *into* the resolution agreement, only that the court must presume a resolution agreement violates the statute. Further, the penalties do not tie back to the alleged infringer, the claimant or the resolution agreement. The penalty section states, "A person that violates or assists in violating this section" and holds them liable for three times the value of the item of value that the alleged infringer received or $10 million "for each violation". What constitutes a violation? What does "assists in violating this section" mean? Are both the claimant and the alleged infringer liable for individually entering into the agreement? Can individuals be held liable and named by the Attorney General separate from a named company and is each party then responsible for a minimum $10 million civil penalty? These are important questions for the committee to consider as you debate SB 764.

SB 764 makes virtually all settlement agreements in these cases potentially unlawful and opens up liability for any pharmaceutical manufacturer who settles a patent case. Given the FTC data shows a vast majority of patent disputes were resolved without compensation or restrictions on generic competition, we urge you to oppose SB 764. If the committee believes settlements in patent cases are actually a driver of prescription drug costs, we would recommend directing DCBS through the Drug Price Transparency program to study the filings from the FTC before moving forward. At a minimum, more information is necessary before enacting legislation that could negatively impact generics coming to market and create this confusing, complicated and expensive litigation exposure. Please oppose SB 764.