SENATE BILL REPORT
SSB 5388

As Passed Senate, March 6, 2023

Title: An act relating to improving diversity in clinical trials.

Brief Description: Concerning improving diversity in clinical trials.

Sponsors: Senate Committee on Health & Long Term Care (originally sponsored by Senators Rivers, Cleveland, Muzzall, Conway, Frame, Hasegawa, Keiser, Lovelett, Lovick, Pedersen, Rolfes, Saldaña, Valdez and Wilson, C.).

Brief History:

Committee Activity: Health & Long Term Care: 2/03/23, 2/09/23 [DPS-WM]. Ways & Means: 2/20/23, 2/23/23 [DPS (HLTC), w/oRec].

Floor Activity: Passed Senate: 3/6/23, 48-0.

Brief Summary of First Substitute Bill

- Establishes a diversity in clinical trials program at the Washington State Institutional Review Board.
- Requires any entity receiving funding from the National Institutes of Health to conduct clinical trials of drugs or medical devices to adopt a policy concerning recruitment of persons who are members of underrepresented demographic groups, provide information in languages other than English, and to provide translation services.
- Requires investigators in clinical trials to collaborate with community-based organizations.

SENATE COMMITTEE ON HEALTH & LONG TERM CARE

Majority Report: That Substitute Senate Bill No. 5388 be substituted therefor, and the substitute bill do pass and be referred to Committee on Ways & Means.

Signed by Senators Cleveland, Chair; Robinson, Vice Chair; Rivers, Ranking Member;

This analysis was prepared by non-partisan legislative staff for the use of legislative members in their deliberations. This analysis is not part of the legislation nor does it constitute a statement of legislative intent.

Muzzall, Assistant Ranking Member; Conway, Dhingra, Holy, Padden, Randall and Van De Wege.

Staff: Kevin Black (786-7747)

SENATE COMMITTEE ON WAYS & MEANS

Majority Report: That Substitute Senate Bill No. 5388 as recommended by Committee on Health & Long Term Care be substituted therefor, and the substitute bill do pass.

Signed by Senators Rolfes, Chair; Robinson, Vice Chair, Operating & Revenue; Wilson, L., Ranking Member, Operating; Gildon, Assistant Ranking Member, Operating; Schoesler, Ranking Member, Capital; Rivers, Assistant Ranking Member, Capital; Warnick, Assistant Ranking Member, Capital; Billig, Boehnke, Braun, Conway, Dhingra, Hasegawa, Hunt, Keiser, Muzzall, Nguyen, Pedersen, Saldaña, Torres, Wagoner and Wellman.

Minority Report: That it be referred without recommendation.

Signed by Senators Mullet, Vice Chair, Capital; Van De Wege.

Staff: Monica Fontaine (786-7341)

Background: The Washington State Institutional Review Board. An institutional review board is a federally-mandated entity that reviews research proposals to assure that the rights and welfare of human subjects are protected, risks to human subjects are minimized and not unreasonable, and that proposed study designs and methods are appropriate.

The Washington State Institutional Review Board (WSIRB) is the designated institutional review board for several state agencies, including the Department of Social and Health Services, Department of Health, Health Care Authority, and Department of Labor and Industries. WSIRB provides regulatory review, approval, and oversight of research that involves state agency clients, beneficiaries, patients, wards, and employees. WSRIB ensures the protection of human research subjects and maintains guidelines addressing various topics related to clinical trials.

Clinical Trials. Clinical trials are research studies involving human volunteers to evaluate medical products like medications, vaccines, or medical devices for safety and effectiveness. In 2016, the United States Food and Drug Administration released a guidance document containing nonbinding recommendations for the collection of race and ethnicity data in clinical trials. The guidance addresses ways to collect more consistent demographic subgroup data by establishing minimum standards for maintaining, collecting, and presenting data on race and ethnicity.

Summary of First Substitute Bill: WSIRB must establish a diversity in clinical trials program to encourage participation in clinical trial of drugs and medical devices by persons who are members of demographic groups underrepresented in clinical trials. WSIRB may:

- collaborate with medical facilities, health authorities, nonprofit organizations, and scientific investigators and institutions to assist in recruiting persons who are members of underrepresented demographic groups to participate in clinical trials;
- establish a website to provide information concerning methods for identifying and recruiting persons who are members of underrepresented demographic groups to participate in clinical trials;
- provide links to entities performing research relating to drugs or medical devices in Washington;
- apply for grants to fund the diversity in clinical trials program; and
- submit a biannual report starting July 1, 2024, to the health care committees of the Legislature.

Any state entity that receives funding from the National Institutes of Health (NIH) to conduct clinical trials of drugs or medical devices must adopt a policy concerning identification and recruitment of persons who are members of underrepresented demographic groups to participate in clinical trials. Investigators conducting clinical trials must collaborate with community-based organizations and use methods to recruit persons who are members of underrepresented demographic groups to participate in clinical trials recognized by the United States Food and Drug Administration. These entities must also provide information to trial participants in languages other than English and provide translation services or bilingual staff for trial screening.

Demographic groups underrepresented in clinical trials may include persons who are underrepresented by race, sex, sexual orientation, socioeconomic status, or age.

Appropriation: None.

Fiscal Note: Available.

Creates Committee/Commission/Task Force that includes Legislative members: No.

Effective Date: Ninety days after adjournment of session in which bill is passed.

Staff Summary of Public Testimony on Original Bill (Health & Long Term Care): *The committee recommended a different version of the bill than what was heard.* PRO: This adventure started six years ago. Applying the bill to all institutions that receive NIH funding is new this year. Thank you UW for working on language. We want to make sure pharmaceuticals work with the same efficacy on women and people of color as they work on the white male population. This will help to assure equity in health care. Over the interim our previous concerns about outreach were resolved. The University of Washington receives close to $1 billion in NIH grant funding and operates many clinical trials. Historical challenges and skepticism of clinical trials exist because of past transgressions; participation by our office of diversity and equity will help. Involving community-based organizations is key to success. Genetic ancestry makes certain patients more susceptible to

different types of cancer, and causes them to metabolize drugs differently. All patients need the same opportunity to participate in new treatments. Patients lose early access to potentially life-saving treatments. Please consider other enhancements to the bill.

Persons Testifying (Health & Long Term Care): PRO: Senator Ann Rivers, Prime Sponsor; Adam Zarrin, Leukemia & Lymphoma Society; Kirsten Smith, Susan G. Komen; Ian Goodhew, UW Medicine.

Persons Signed In To Testify But Not Testifying (Health & Long Term Care): No one.

Staff Summary of Public Testimony on First Substitute (Ways & Means): PRO: There are challenges increasing diversity in clinical trials. Diversity in clinical trial participants isn't required by the federal government unless those participants are a subject of the clinical trial. This would allow us to recruit participants and interpret and translate for trials. The volume of trials at UW is why the fiscal note is so high. Black women are dying at higher rate of cancer and heart disease. The longer drugs are prescribed that are not tested on that population, the more those numbers will continue to rise. The fiscal note is significant because there are challenges to increasing diversity participation in clinical trials. This is an estimate of what it would take to both recruit participants, then translate and interpret for them in trials.

Persons Testifying (Ways & Means): PRO: Senator Ann Rivers, Prime Sponsor; Ian Goodhew, UW Medicine.

Persons Signed In To Testify But Not Testifying (Ways & Means): No one.