To the Honorable Members of the Senate Committee on Health who have scheduled a public hearing on Wednesday, January 30, 2008, @ 1:15 p.m. in Room 016 on a bill relating to affordable prescription drugs

Aloha kakou,

I would like to voice my support of S.B. 2534 in that "containment" and "affordable access" to prescription drugs is something I hear about from many kupuna. Some of these voices are from my very own 'ohana. I'm sure those of you reading this also have this experience. I understand prescription drugs to be "intellectual property" and "business products". Because this is so, even though public funds help pay for the research that developes these drugs, there are costs that need to be passed on to the consumer. However, I believe that these rising costs, especially for frail elderly and disabled, many of whom are in fixrd income and "under insured", need to contained and brought into the realm of affordable. There are "best practice" cost control programs in other states and I believe kupuna, the disabled and others in Hawai'i deserve to know what they are and to be given the chance to universally participate.

Me ka mahalo pono,
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HAWAII ALLIANCE FOR RETIRED AMERICANS (HARA)
AN AFFILIATE OF THE ALLIANCE FOR RETIRED AMERICANS
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TO: SENATE-SGT-AT- ARMS

JANUARY 26, 2008
Fax 586-6659

FROM: Bruce McCullough
HARA Legislative Committee, Chair

FOR: COMMITTEE ON HEALTH
Senator David Y. Ige, Chair
Senator Carol Fukunaga, Vice Chair

COMMITTEE ON HUMAN SERVICES AND PUBLIC HOUSING
Senator Suzanne Chun Oakland, Chair
Senator Les Ihara Jr., Vice Chair

RE: SB-2534 Relating to Prescription Drug Cost Containment & Affordable Access

DATE: Wednesday, January 30, 2008

TIME: 1:15 P.M.

PLACE: Rm 016

I am submitting testimony on behalf of the Hawaii Alliance for Retired Americans (HARA). HARA represents over 17,000 retirees, members of numerous organizations and individuals. HARA is a chapter of the Alliance of Retired Americans (ARA), a national advocate for seniors and retirees with over three (3) million members.

HARA is in strong support of this proposed legislation.

The bill would create a pharmacy best practices and cost control program that is designed to reduce the cost of providing prescription drugs while

maintaining high quality in prescription drug therapy.

This bill is modeled after a Vermont law which was enacted on June 13, 2003.

Like other legislation that will be introduced, this bill will help make prescription drugs more affordable as well as keeping quality of the drugs high for the residents of Hawaii.

The bill will also deter pharmaceutical representatives from unduly influencing the individuals who are responsible for prescribing, dispensing and purchasing prescription drugs.

January 29, 2008

TO: Chair David Y. Ige and Members of the Senate Committee on Health, and

Chair Suzanne Chun Oakland and Members of the Senate Committee on Human Services & Public Housing

FROM: Pharmaceutical Research and Manufacturers of America
(Norman H. Suzuki)

RE: **SB 2534** Relating to Prescription Drug Cost Containment and Affordable Access

Hearing Date: 1/30/08 at 1:15 p.m.

My name is Norman Suzuki. I am a representative of the Pharmaceutical Research and Manufacturers of America ("PhRMA"), which is a trade association of the country's leading research-based pharmaceutical and bio-technology companies, which are in the business of making medicines.

PhRMA respectfully **opposes** passage of **SB 2534** for the reasons set forth in the attached statement.

Thank you for considering this testimony. We respectfully request that the Committees hold this measure.

In Opposition to Hawaii Senate Bill 2534

January 28, 2008

PhRMA opposes SB 2534 because it imposes price controls, jeopardizes existing federal programs, and restricts patient access to the best drug therapy, thus threatening patient health.

SB 2534 proposes several cost containment programs and strategies that are unfriendly to patients, particularly patient access to the best drug therapy. These programs include a statewide preferred drug list (PDL); prior authorization; supplemental rebates; aggregate purchasing including Medicaid; a multistate purchasing consortium; disclosure of drug makers' proprietary and business information; and a pharmacy discount plan which could leverage Medicaid.

Pharmacy discount plan

As drafted, SB 2534 would create a pharmacy discount plan for Medicare-eligible residents with household income up to 400% Federal Poverty Level (FPL) and any other Hawaii resident with household income up to 300% FPL. PhRMA opposes this on the grounds it would likely require pharmaceutical manufacturers to enter into rebate negotiations with the state for these non-Medicaid populations. A program like this would likely obtain supplemental rebates or discounts that may be equal to Medicaid best price – by using a preferred drug list and threat of prior authorization to obtain these discounts – as was once attempted through legislation in the State of Maine, but quickly ruled against in a court of law before it could be enacted.

The proposed SB 2534 pharmacy discount program could limit Medicaid patients' access to needed medications in order to force manufacturer discounts for a non-Medicaid population. Under federal law implementation of such a program that threatens to alter state Medicaid programs requires approval from the Department of Health and Human Services (HHS). In recent years, HHS has made it clear where it stands on approving State Plan Amendments (SPA) that seek to leverage the Medicaid population for discounts to other populations. Essentially, the state must demonstrate that the program will further the goals and objectives of the Medicaid program – something that numerous states have attempted in years past, but rarely receive considering that the Center for Medicare and Medicare Services has never approved a request for Medicaid up to 300% of FPL.

A Statewide PDL can Hurt Patients and Increase Costs

Government prior authorization systems can result in the denial of the most appropriate drug therapy, ultimately increasing the use of other, more expensive services, such as hospitalization and emergency room visits. Furthermore, limiting medications available to Medicaid patients by creating a PDL and imposing access barriers on patients who need non-preferred medications runs contrary to today's medical standards and existing Medicaid law. Additionally, containing cost through reducing drug access, such as through prior authorization, ignores the value of pharmaceuticals to patients and the cost of more expensive healthcare alternatives. A PDL creates a *de facto* formulary which interferes with the doctor-patient relationship by preventing prescribers from being able to select the best patient drug therapy. Often recently-approved products, without a generic version, offer patients advantages with regard to clinical efficacy and disease prevention. Some newer therapeutic agents may be associated with a more tolerable side effect profile and less frequent dosing requirements that can facilitate patient compliance with the prescribed treatment; thereby improving the overall health of the patient and reducing future health care expenditures.

Aggregate Purchasing Could Decrease Private Coverage of Prescription Drugs

As drafted, SB 2534, would utilize Hawaii's buying power to negotiate prices and purchase prescription drugs for several groups, including state-funded programs and, in some cases, Medicaid. This may address the prescription drug needs of one patient population at the expense of another. Aggregate purchasing which includes Medicaid could impact the Medicaid best price rule. While impossible to predict what individual companies may do in negotiations, the Medicaid best price law, coupled with a proposed aggregate purchasing program, could create uncertain consequences in those negotiations. Moreover, permitting private sector entities to enroll separately could unintentionally decrease private coverage of prescription drugs.

Multistate Purchasing Can be Harmful to Patients

SB 2534 contemplates Hawaii's participation in a multistate purchasing program. From a patient's perspective, multistate purchasing program can be onerous to effective and appropriate treatment options. Michigan and four other states, for example, maintain such a program that requires all of the drugs that are used to treat the "same" condition to meet the same reference price, cost, and not a patient's access to needed medicines prescribed by their physicians. Patient health, not cost-savings for a state, should be the driving force for any pursued program.

Trade Secrets are Legally Protected Property.

As proposed, SB 2534 requires pharmacy benefits managers doing business with manufacturers to disclose proprietary information related to private agreements, including rebates and discounts, which likely violates federal Medicaid and fair trade practices law, as well as trade secrets. Disclosure of the agreed upon terms for one client might dampen the level of competition in drug negotiations with other clients and thus, paradoxically, increase health care costs. Given the secrecy and competitive value of marketing activities, Hawaii courts are likely to recognize this information as a trade secret and not available to the state for public use or distribution. While the bill prohibits the public disclosure of information revealing company-identifiable trade secrets, SB 2534 does not adequately describe procedures the state will implement to ensure confidentiality of the information, which could result in disclosure of proprietary financial agreements with drug manufacturers. Further, the bill does not indicate the extent of the state's liability and a drug maker's recourse for the unauthorized disclosure of protected trade secrets. The bill could constitute a violation of federal trade secret law.

Strict Federal and PhRMA guidelines make SB 2534's marketing disclosure provisions unnecessary, duplicative and potentially costly to the state.

Pharmaceutical manufacturers are subject to criminal anti-kickback statutes and other criminal and civil provisions, enforced by the U.S. Department of Justice, that govern their relationships with healthcare providers, including the *Food, Drug, and Cosmetic Act,* the *Federal Anti-Kickback Statute, Prescription Drug Marketing Act,* the *Federal Trade Commission Act,* and the *False Claims Act.* Furthermore, the Federal Health and Human Services Office of Inspector General (OIG) maintains detailed guidance for pharmaceutical companies designed to deter violations of these federal laws. These marketing guidelines prohibit *quid pro quos* between drug makers and healthcare professionals. Furthermore, the pharmaceutical industry has issued its own voluntary guidelines, *The PhRMA Code for Interactions with Healthcare Professionals* (the "PhRMA Code"), related to communications with healthcare practitioners. Requiring an additional layer of reporting and monitoring, requires either an expansion of a pre-existing state agency or creation of an entirely new one - both of which seem unnecessary, given the presence of both the PhRMA Code and OIG guidance, and existing legal sanctions for unlawful behavior. Furthermore, pursuing legislation that would require new agency oversight could increase the financial and administrative resource burdens of the state.

For the reasons stated above, PhRMA opposes Hawaii Senate Bill 2534