

**MERRILL R. JACOBS**  
**Deputy Vice President**  
**State Government Affairs**



March 24, 2015

Honorable David Chiu  
Member of the Assembly  
Room 2196, State Capitol  
Sacramento, CA 95814

**RE: AB 463 (Chiu)**  
**PhRMA position: Oppose**

Dear Assembly Member Chiu:

The Pharmaceutical Research and Manufacturers of America has reviewed your Assembly Bill 463 and adopted an oppose position. While we appreciate you reaching out to discuss the measure with the pharmaceutical industry, Assembly Bill 463 would create new burdensome reporting requirements on an industry that should otherwise be dedicating its resources to bringing new therapies and cures to prescribing physicians and their patients.

You have indicated you are seeking cost transparency associated with drug company research and development, clinical trials, marketing and other operational functions. There seems to be an underlying assumption in the bill that a company engaged in new drug development will be able to easily generate the data sought by the bill. This information will be difficult to ascertain, and complying with the reporting requirements imposed in the bill will be costly for the life sciences industry.

Following are our principle objections to AB 463:

1. The bill requires disclosure of the “total research and development costs paid by the manufacturer ... in the development of the drug.” In some cases these numbers will be impossible to determine because the cost of developing one drug cannot be separated from the cost of a similar product that failed in the clinical trial process. Indeed, some research costs may be in a 20-year research stream.
2. The “total costs of clinical trials” is a closely guarded, proprietary number. Every pharmaceutical company handles their clinical trials differently, and for a variety of reasons the company does not want this data to fall into the hands of their competitors.
3. The bill seeks total cost information regarding “other costs to acquire the drug, including ... purchase of patents, licensing or acquisition of any corporate entity owning any rights to the drug ...” If a company purchased another business, the terms and conditions of the transaction are often kept confidential by contract.
4. Not only are pharmaceutical companies targeted by AB 463 obligated to report a plethora of financial information, the bill goes on to stipulate the reporting company must secure an audit of what is being disclosed “by a fully independent third-party auditor prior to the filing.” Why is this extra layer of reporting and expense necessary?

*Pharmaceutical Research and Manufacturers of America*

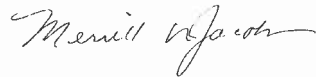
5. What will become of the data reported? The Office of Statewide Health Planning and Development is required to write an annual report “outlining the information submitted.” What then? After companies large and small go through the task of compiling the data to be disclosed and report it to OSHPD, who will benefit? Where is the utility of documenting one company spending \$500 million to perform the research and development of a cancer therapy and a different company spending \$750 million on a pulmonary medicine?

6. Finally, the bill requires reporting on products that have been approved by the FDA. There is no provision for reporting the cost of developing medicines that fail to make through all stages of a clinical trial.

No other state requires such documentation. The Federal Food and Drug Administration does not ask for these numbers. Medicare and Medicaid, two of the nation’s largest drug purchasers do not seek such sensitive information. We see no compelling reason for the State of California – where much of the world’s biotechnology research and development takes place – to impose these new reporting requirements on the pharmaceutical industry.

Please let us know if you would like to discuss further. Thank you for your attention to our position.

Sincerely,

A handwritten signature in cursive script that reads "Merrill R. Jacobs".

Merrill R. Jacobs

cc Chair and Members, Assembly Health Committee