SB 1092

LINDA LINGLE
GOVERNOR OF HAWAII

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STATE OF HAWAII
DEPARTMENT OF HEALTH
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In reply, please refer to:
File:

Senate Committee on Health

SB 1092, RELATING TO PRESCRIPTION RECORDS PRIVACY

Testimony of Chiyome Leinaala Fukino, M.D.
Director of Health

February 11, 2009
3:00pm

Department's Position: The Department appreciates the intent of this bill, but has concerns regarding this proposal; and therefore, respectfully opposes this bill.

Fiscal Implications: As yet, unquantified resources will be needed for rule making and other implementation.

Purpose and Justification: This bill amends HRS Chapter 328 by adding additional language to protect the confidentiality of prescription records by prohibiting the use of such information for marketing purposes. The bill also requires State compliance with federal restrictions on the transfer and use of Medicaid data.

We appreciate the intent of this measure to protect personal medical information from the potential abuse by unauthorized entities. However, we consider this measure unnecessary as HRS Section 328-16 already addresses the confidentiality of information contained in a prescription order; and this issue is addressed by the federal Health Insurance Portability and Accountability Act (HIPAA).

Further, the bill appears to require the Department to provide oversight on how the Department of Human Services (DHS) is complying with Federal Medicaid laws on how prescription information is used. We are unaware of confidentiality breaches by the DHS; and even if there were, we think the

issue is outside of the intent and scope of HRS Chapter 328, which is a food, drug, and cosmetics safety law, and should be dealt with another way.

For these reasons, the Department recommends this measure be deferred.

Thank you for the opportunity to testify.

February 10, 2009

TO: Chairman David Y. Ige and Members of the Committee on Health

FROM: Pharmaceutical Research and Manufacturers of America
(William L. Goo)

RE: **SB 1092** - Relating to Prescription Records Privacy

Hearing Date: Wednesday, February 11, 2009 at 3:00 p.m.

My name is William L. Goo. I represent Pharmaceutical Research and Manufacturers of America (PhRMA).

PhRMA respectfully opposes passage of **SB 1092.** Attached is PhRMA's testimony in opposition.

Thank you for considering this testimony. It is respectfully requested that the Committee hold this measure.

Statement PhRMA

In Opposition to Hawaii Senate Bill 1092

Position: PhRMA respectfully opposes prohibitions on the commercial use of physician prescribing data as proposed in Senate Bill 1092.

Banning the use of prescribing data could result in significant unintended consequences that could adversely impact patient care and safety and hamper manufacturers' ability to alert physicians to important new drug information. This data is critical to the efficient, timely, and targeted dissemination of information to doctors and patients. The data used by manufacturers does not contain patient identifiable information and allows prescription drug manufacturers to carry out federally required drug programs that help safeguard patients, helps companies address other patient safety concerns, and can help reduce the cost of prescription drug marketing.

Patient Identifiable Information Is Protected

The Health Insurance Portability and Accountability Act of 1996 (HIPAA) bars any unauthorized use of patient identifiable information. Therefore, under federal law, prescriber data cannot include individual patient identifiable information.

Critical Value of Prescriber Data Reinforced by US Congress

The federal regulatory system increasingly depends on pharmaceutical companies to communicate directly with health care providers about how to use medicines safely and effectively. This communication allows drugs with significant benefits, but serious safety risks, to be made available to patients. Without prescriber data, such communication will be less efficient.

The critical nature of prescriber data was recently recognized by Congress in the Food and Drug Administration Amendments Act of 2007 (FDAAA). The FDAAA authorizes the FDA to require Risk Evaluation and Mitigation Strategies (REMS) for certain high risk medicines. These structured, required programs are intended to increase safeguards for patients when FDA believes that extra vigilance is needed.

A REMS can require manufacturers to: ensure that prescribers have specific training, experience or certification; disseminate information about the REMS to health care providers; ensure that a drug is dispensed to patients only "with evidence or other documentation of safe-use conditions, such as laboratory test results" or if "each patient using the drug [is] subject to certain monitoring;" and monitor, evaluate, and improve the implementation of REMS.

Complete access to prescriber data is necessary to train providers and monitor REMS. This is because, most importantly, one cannot predict in advance which drugs will be the subject of a REMS (e.g., a safety issue can be identified after FDA approval). Drug manufacturers will need access to prescriber data for compliance so it is important that access to prescriber data is not limited to only when required by federal law.

The importance of REMS is further emphasized by the penalties for non-compliance. Manufacturers will be subject to $250,000 per violation; $1 million for all violations adjudicated in a single proceeding; and $10 million for all violations adjudicated in a single proceeding if the violations continue after written notice from FDA for failing to comply with REMS requirements.

Other Patient Safety Concerns

Because pharmaceutical companies generally sell their medicines to wholesalers (who in turn sell to pharmacies), without prescriber data manufacturers do not have direct knowledge of which health care professionals prescribe their medicines. For example, without access to prescriber data, it becomes extremely difficult for pharmaceutical companies to conduct targeted and effective drug recalls; identify and report to FDA any adverse events associated with a medicine; and efficiently distribute new drug labeling information such as drug-drug interactions and black box warnings.

Additionally, prescriber data contributes significantly to the acceleration of clinical trials by identifying physicians most likely to have pools of patients eligible for enrollment. Analysis of prescriber data also helps efforts to identify: physicians from whom to solicit information on unmet medical needs (for use in the development of new medicines or new formulations of existing medicines); specific patient populations for targeted sales and marketing of pharmaceuticals; prescribers who are not treating patients optimally (e.g. under-prescribing for high cholesterol); and physicians whose patients could use samples.

Access to Prescriber Data Allows Manufacturers to Focus Outreach Efforts on Providers and Patients

Continued access to prescriber data can help pharmaceutical manufacturers reduce the cost of marketing by preventing expensive, blanketed marketing of prescription medicines. Banning the commercial use of this data may hinder the ability of prescription drug manufacturers to effectively target the dissemination of necessary clinical information and drug samples to those physicians most likely to need education on certain prescription and require specific drug samples for their patient populations.

The AMA PDRP Allows Physicians to Restrict the Use of Their Prescribing Data

The AMA's PDRP provides physicians with an opt-out mechanism to prohibit the release of their prescribing data to pharmaceutical sales representatives for a period of three years. Physicians can also register complaints against companies or individuals who have used prescriber data inappropriately through the PDRP. Physicians may easily opt-out by logging on to **www.ama-assn.org/go/prescribingdata** or by requesting the restriction via phone, fax, email, or standard mail. Pharmaceutical companies must ensure compliance with the PDRP by processing restriction requests within 90 days.

Prescriber data does not contain patient identifiable information, allows prescription drug manufacturers to carry out federally required drug programs that help safeguard patients, helps manufacturers address other patient safety concerns, and can help reduce the cost of prescription drug marketing.

For these reasons, PhRMA urges Hawaii senators to oppose efforts to ban the use of physician prescribing data.

Eisai Inc.

100 Tice Blvd., Woodcliff Lake, NJ 07677

February 11, 2009

The Honorable David Ige
Chair, Health Committee
Senate
State of Hawaii

Re: SB 1092

Dear Mr. Chairman and Members of the Committee:

I am writing to you on behalf Eisai Inc. (Eisai). Eisai opposes SB 1092, which imposes restrictions on the sale and use of prescriber-data, because it could hinder the physicians' access to the most recent information on prescription drugs, adversely impacting patient health and safety. Eisai supports physicians possessing all the necessary information to prescribe appropriate medications and to manage a patient's prescription therapy. Eisai must oppose SB 1092, unless exceptions are made for chronic and seriously debilitating, or life-threatening diseases.

Eisai is proud of its human health care *(hhc)* mission that strives to bring new, life-saving and enhancing prescription drugs to patients in the most effective and efficient way possible. We discovered and provide Aricept®, the only therapy approved for mild, moderate and severe Alzheimer's disease, and we have an extensive oncology product line. Eisai is proud to have four (4) orphan disease drugs that enhance the lives of patients with severe and disabling diseases that have population demographics fewer than 200,000, such as myelodysplastic syndrome, a condition of oncologic origin. Eisai provides BANZEL™ for a population of approximately 89,000 that treats Lennox-Gastaut Syndrome, a severe epilepsy disorder that accounts for one (1) to four (4) percent of all epilepsy cases.

Physician data is used to provide timely, efficient, and targeted dissemination of information to doctors and patients. Prescriber-data does not include patient-identifiable information, which is protected information under the Health Insurance Portability and Accountability Act (HIPAA). Eisai understands the privacy concerns regarding prescriber-data, and that is why Eisai supports the efforts of the American Medical Association's Prescription Data Restriction Program (PDRP), which strikes a balance between conflicted physicians by providing an opt-out from release of their prescription data, and others who can receive up-to-date safety information on the medicines they frequently prescribe.

Without the ability to use prescriber-data smaller and mid-size biotechnology companies may face increased barriers in trying to bring a drug to market because it will become more cumbersome and costly to educate physicians about their drugs. Many drugs made by smaller manufacturers are approved under the Orphan Drug Act, which defines an orphan disease as one that afflicts fewer than 200,000 individuals. Eisai manufactures drugs like ONTAK®, approved for cutaneous t-cell lymphoma (CTCL)—a rare, slowly progressive form of non-Hodgkins lymphoma and orphan disease—as well as the aforementioned Aricept®. As a mid-size company, not being able to target its communications with prescribers could make the cost to educate physicians about ONTAK®, Aricept® or other medicines prohibitive. Ultimately, this would put downward pressure on future research and development on orphan diseases and diseases with small demographic populations, such as myelodysplastic or Lennox-Gastaut syndromes.

Access to prescriber-data allows pharmaceutical companies to target necessary prescription information to specific physicians, which helps avoid clinicians in a broader audience from being overwhelmed by less-relevant information. For example, it would not typically make sense to target information or samples for cancer medicine to a cardiologist, neurologist, or gastroenterologist. With respect to sampling, legislation such as SB 1092 that restricts information for the targeting of samples can also interfere with the value of these programs. Samples provide value to patients by allowing them to try prescription therapies before prescriptions are filled. Programs should not interfere with or make it hard for manufacturers to provide free samples.

Pharmaceutical manufacturers use prescriber-data to enhance patient safety as described above, but this information is also necessary to comply with various federal regulations and reporting requirements and quality initiatives.

- **Patient Medication Adherence** for chronic conditions**:** Use of prescriber-data can reinforce appropriate adherence to prescription medicinal therapies for chronic and seriously debilitating, or life-threatening conditions, which may help reduce costs in the long term.
- **"Risk Management Plan":** The Food and Drug Administration (FDA) may require a manufacturer to implement a 'risk management plan' for specific safety concerns. In these instances, Eisai may be required to monitor and ensure that prescribers are conveying essential safety information to patients. In these instances, prescriber-data restrictions may jeopardize patient safety for life-saving and enhancing drugs for diseases such as cancer, leukemia, Alzheimer's disease, and epilepsy.
- **Adverse health reporting:** Manufacturers, including Eisai, are required by federal law to report to the FDA any adverse event associated with an approved drug. Prescriber-data is useful in obtaining the necessary information regarding adverse events.
- **Drug recall:** In rare instances, prescriber-data is used when FDA regulations require that companies notify physicians about drug recalls.
- **Labeling changes:** Targeted communications are one of the ways in which companies like Eisai may notify physicians of important changes in safety information, including black box warnings, drug-drug interactions, and emerging adverse events.

For these reasons, Eisai urges the Committee to reject SB 1092 and its restrictions on commercially available prescriber-data, allowing prescribers to opt-out of these programs, or at a minimum, allow exemptions for programs in place for chronic and seriously debilitating, or life threatening conditions.

If you have any additional questions or concerns, please do not hesitate to contact me at (201) 746-2553 or at ray_frost@eisai.com.

Sincerely,

/s/

Ray Frost
Senior Director
Federal and State Affairs

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Date: February 11, 2009

The Honorable David Ige,
Chair of the Senate Health
Committee

Re: Senate Bill 1092

Madam Chair and Members of the Committee,

IMS Health is a health information company that provides services to a diverse range of healthcare stakeholders in the public and private sectors in over 100 countries around the world. Our primary interest is in preserving the critical data assets and the *flow of anonymous* data which our nation will need to face the *serious* healthcare challenges ahead, and to continue efforts to improve quality and longevity for our population at an affordable price. We support efforts to protect the privacy of personal health information for patients and applaud your efforts to do so. Our own policies and practices to protect patient privacy include multiple encryption techniques and many overlapping safeguards so that the data we provide to assist healthcare stakeholders in no way allow identification of individual patients.

IMS also understands the need to manage healthcare costs. Collectively, our quality of life depends upon it. We applaud efforts to manage utilization, chronic illnesses, and to increase the appropriate use of generics, which now represents over 70% of all prescribing in this country. We are aware of healthcare reform initiatives, and the complex set of alternatives and possible solutions under consideration at the state and federal levels of our government, such as HIT, universal healthcare, pay for performance and personal accountability. It is our hope that IMS Health data assets will enable this important effort and protect patients by optimizing their care with evidence-based information.

In the context of that necessary debate, it is clear to us is that information will be absolutely necessary to enable these initiatives to succeed. Otherwise, it could be compared to performing surgery with blind folders. We will make trade-offs without knowledge of the risks and opportunities...and patients care will be compromised.

It is also of great importance to us that the principals that will guide healthcare reform going forward are protected and preserved today. That is why IMS is against data restriction laws which impede the free flow of important information that does not compromise the privacy of individual patients. These legislative proposals undermine the principal of transparency, which is a guiding principal in healthcare reform, repeatedly

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expressed by all health experts, agencies and thought-leaders of both political parties as well as AARP, SEIU, and a host of consumer advocacy organizations.

Legislative efforts to restrict data to specific stakeholders in the healthcare system have been justified over time by a changing set of rationales, with little if any substance in facts. Initially, they were framed by their proponents in the context of patient and physician privacy to garner support and raise the level of fear around this issue when, in fact, no such risk exists. Today, we hear very little about privacy. Furthermore, two Federal Judges have said there is no privacy issue, supporting our contention that there was intentional exaggeration by some of the proponents of these bills in the first place.

When these arguments failed, it was suggested that these laws would reduce costs. This is a popular theme, but to date there is no information to support such conclusions; and there is significant information to the contrary that suggests marketplace practices already exist to manage cost, without the need for data restrictions that may compromise patient care:

- New Hampshire restricted these data for approximately 9 months in 2006-2007; with no impact on costs. If the availability of these data drives costs, how does one account for that?
- The dispensing of new brand medications (products with a market presence of 3 or less years) has declined from 5.7% of total prescriptions dispensed in 2003 to only 1.3% in 2008. At the same time, generic medication grew to represent approximately 70% of dispensed prescriptions in 2008. How would that lead one to conclude that these data were causing physicians to prescribe brand medications inappropriately?
- From 1999 to 2007, the use of prescriber-level data by pharmaceutical research company representatives increased by nearly 56% while the annual rate of prescription drug spend growth plummeted from over 15% to only 1.6%.
- Of particular importance, managed care practices are much more influential in determining what is dispensed. Based on clinical and cost considerations, using active formulary management, patient education, tiered co-pays, and offering patients lower-cost equivalents (generic or brand) when appropriate, managed care continues to lower costs. And they have done so in spite of price increases and a 31% increase in the overall number of prescriptions dispensed from 2003 to 2008.
- Managed Care practices are well established and effective in managing utilization and costs. Today, generic prescribing uptake and share have achieved a national average of 70% of dispensed prescriptions. Once again, how would one conclude that payers in the public or private sectors were being over-run by rampant or irrational prescribing practices?

These laws risk patient care by intentionally impeding the process that brings medical breakthroughs to patients on a timely basis.

- Slowing this process effectively delays treatment. That means patients who can benefit from newer medications may be harmed.
- This law affects all products regardless of patient benefit. Life-saving medications and documented advances will be impacted the same as marginal improvements. At a minimum to protect patients, the legislation should provide for an exception for proven medical breakthroughs (so-called "fast tracked drugs as determined by the

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FDA), cancer medications, life-saving therapies, safety warnings from the FDA, etc.? No such language exists in the bill.

Proponents of these laws say the medical marketplace will disseminate all the information required for patient care when in fact recent studies published in the NEJM showed that patients are not routinely treated according to best practices. Further, the Institute of Medicine indicated that dissemination of proven practices throughout the healthcare system can take as long as 17 years!

In light of these problems and needs, IMS suggests that you are now considering legislation that would remove one of the tools that supports quality improvement and education.

Lastly, legislation restricting these anonymous data risks the health of a robust biotechnology industry.

As you will hear from the Montana Bioscience Alliance, these data allow a more efficient process for bringing medical innovation to patients. Without them marketing costs will increase and there will be a need for a relatively larger sales force. This information allows small companies to compete with large companies and fuels the emergent biotech companies that employ small sales forces to reach few physicians...who treat the small populations who may benefit ***(The proverbial needle in a haystack).***

Finally we object to the idea that Government should decide who has access to and use of information Government deciding to block the flow of information because it wants to control behavior represents a very dangerous precedent.

In conclusion, IMS believes that House Bill 394, if enacted, will ultimately hurt patients. We urge you to vote against its passage.

While this testimony is submitted without our being present, IMS would be pleased to respond to questions should they arise by the Members of this Committee.

Respectfully submitted,

Randolph Frankel

Randolph Frankel
Vice President, IMS Health