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Civil No. 06-1-0720-04 EEH
(Complex Litigation)



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ATTORNEYS FOR PLAINTIFF

IN THE CIRCUIT COURT OF THE FIRST CIRCUIT
STATE OF HAWAII

State of Hawaii,

Plaintiff,

vs.

Abbott Laboratories Inc., et al

Defendants.

Civil No. 06-1-0720-04 EEH
(Complex Litigation)

PLAINTIFF'S RESPONSE TO
DEFENDANT ASTRAZENECA
PHARMACEUTICALS LP AND
ASTRAZENECA LP'S FIRST
REQUEST FOR ANSWERS TO
INTERROGATORIES

No Trial Date Set

PLAINTIFF'S RESPONSE TO DEFENDANT ASTRAZENECA
PHARMACEUTICALS LP AND ASTRAZENECA LP'S
FIRST REQUEST FOR ANSWERS TO INTERROGATORIES

Plaintiff State of Hawaii Department of Human Services hereby responds to Defendants' First Request for Answers to Interrogatories.

PRELIMINARY STATEMENT

Information provided in these responses is based on such information as is presently available to Plaintiff. Plaintiff expressly reserves the right, without assuming any duty not required by the Hawaii Rules of Civil Procedure, to supplement these responses when and if additional information or documentation comes to its attention.

Plaintiff makes these responses without waiving its right to revise, correct, add to, or clarify its responses.

Each response is subject to all objections as to competence, relevance, materiality, propriety, admissibility, privilege, privacy, and the like, and any and all other objections on the grounds that would require the exclusion of any response herein if such were offered in court, all of which objections and grounds are reserved and may be interposed at time of trial.

Plaintiff's objections and responses herein are subject to all applicable protective orders, case management orders, and other directives of the First Circuit Court, other courts of competent jurisdiction and other State Attorneys General and law enforcement agencies.

No incidental or implied admissions are intended in these responses. That Plaintiff has responded to all or any part of a request should not be taken as an admission that Plaintiff accepts or admits the existence of any fact(s) set forth or

assumed by that request or that Plaintiff's response constitutes admissible evidence. That Plaintiff has responded to all or any part of a request also is not intended to be, and shall not be, a waiver by Plaintiff of all or any part of its objection(s) to that request.

Plaintiff's responses are based upon reasonable, diligent investigation heretofore, and are submitted in good faith; however, Plaintiff has not completed its investigation of the facts relating to this case, discovery in this action, or preparation for trial.

GENERAL OBJECTIONS

The following objections apply to Defendants' Requests in their entirety (including Defendants' instructions and definitions) and apply to the Response to each specifically numbered Request. The General Objections are incorporated by reference into each individual Response and will not be repeated in individual Responses unless necessary for clarification.

The Department of Human Services is the single state agency responsible for administering Hawaii's Medicaid program on whose behalf this suit is brought. Plaintiff objects to the definitions of "Plaintiff", "you", "your", "State" or "Hawaii", "Identify", "state the basis" and General Instructions Nos. 1, 2, 3 and 4 on the grounds that said definitions and general instructions are overly broad, cumulative, unduly burdensome, and impose discovery obligations that are beyond the scope of Plaintiff's obligations under the Hawaii Rules of Civil Procedure, and to the extent that they seek to impose on the Plaintiff the obligation to respond for, or produce documents maintained by other branches or agencies of the Hawaii State Government not involved in the operation of the Hawaii Medicaid program.

Plaintiff objects to the Requests to the extent they seek information or documents within the public domain. Information or documents within the public domain include, without limitation, information and documents available to the public on the website maintained by the Hawaii Department of Human Services at <http://www.hawaii.gov/dhs/>, on the website maintained by the Hawaii Med-Quest program <http://www.med-quest.us/>, on the website maintained by ACS State HealthCare at <http://www.himed-questffs.org/>, (the pharmacy benefit manager for the fee for service program) on the website maintained by First Health Services at <http://www.hawaii.fhsc.com>, (preferred drug list information, Pharmacy and Therapeutics Committee, etc.), on the website maintained by the Hawaii Legislative Reference Bureau at <http://hawaii.gov/lrb/>, on the website maintained by the United States Department for Health & Human Services, Centers for Medicare and Medicaid Services at <http://www.cms.hhs.gov/>, and on the website maintained by AdminaStar Federal at <http://www.adminastar.com>.

Plaintiff objects to the Requests to the extent they seek information or documents that are exclusively, or that are already, within in the possession, custody, or control of Defendants or Defendants' counsel.

Plaintiff objects to each Request to the extent that it seeks information or documents that are protected from disclosure pursuant to a protective order entered by a court of competent jurisdiction or confidentiality agreement to which Plaintiff is a party. Such protective orders and confidentiality agreements include, but are not limited to the following:

- (a) Protective Order in *State of Florida ex rel. Ven-A-Care of the Florida Keys, Inc. v. Boehringer Ingelheim Corp; Dey, Inc.; Dey, L.P.; EMD Pharmaceuticals Inc.; Lipha, S.A.; Merck, KGaA; Merck-Lipha, S.A.; Schering Corp.; Schering-Plough Corp; Roxane*

Laboratories, Inc.; and Warrick Pharmaceuticals Corporation. Civil Action No. 98-3032A, Leon County, Florida.

- (b) Protective Order in *State of Texas ex rel. Ven-A-Care of the Florida Keys, Inc. v. Dey, Inc.; Roxane Laboratories, Inc., Warrick Pharmaceuticals Corp.; Schering-Plough Corp.; and Schering Corp.* Case No. GV002327, Travis County District Court.
- (c) Confidentiality Agreement between the California Attorney General's Office and Abbott Laboratories, pursuant to initial administrative subpoena dated September 18, 2000.

The protective orders identified above were entered at the request of the Defendant(s) in those cases. Under the terms of the protective orders, Hawaii is prohibited from the further production or disclosure of documents subject to the protective orders absent an order authorizing the production or disclosure from the court that entered the protective order or a written authorization of the party that produced the documents in that action.

Plaintiff objects to the Requests to the extent that they seek documents relating to the Hawaii's "government knowledge" of Defendants' deceptive practices, which information is not relevant and not likely to lead to the discovery of admissible evidence.

INTERROGATORY NO. 1

Identify all person(s) currently or formerly employed by you or serving as a contractor to you who has personal knowledge of the facts concerning the allegations in the Complaint and their current or previous positions(s) or title(s).

ANSWER:

Objection: The defined terms improperly require Plaintiff to answer subparts or sub-questions in the response causing the interrogatories to greatly exceed the number allowed by HRCF rule 33 and RCC rule 30(b); this question is vague, ambiguous, overly burdensome and oppressive.

The fraud alleged in the Complaint was concealed by the Defendants from the Plaintiff and, therefore, there is no Medicaid Agency employee with personal knowledge of Defendant's concealed fraudulent conduct. This conduct will be established through Defendants' own employees and documents, as well as through the witnesses and documents of third parties, including, among others, Defendants' customers. A component of the fraud consists of the prices reported to Hawaii Medicaid, and Hawaii

Medicaid employees have certain knowledge concerning the prices reported regarding Defendants' drugs and the prices paid by Hawaii Medicaid for those drugs. However, the persons at Hawaii Medicaid with the most knowledge of this information have not yet been identified. Defendants' have not yet fully responded to the Plaintiff's longstanding discovery requests. Until further discovery is conducted and completed, the Plaintiff is unable to identify the persons with the "most knowledge" concerning Defendants' fraud.

Without waiving the objection Plaintiff answers the following persons have knowledge of the Med-Quest program:

Charles Duarte, division administrator (July 1997 – Aug. 2000)

Aileen Hiramatsu, division administrator (2000-200?)

Steven Kawada, assistant administrator (1994 – 2006)

Wesley Mun, acting administrator 2006-2007

Lois Lee, acting administrator (current)

Lynette Honbo, M.D. medical consultant, medical standards branch acting administrator (1994 – 2007)

Rubin Shimazu assistant administrator (1997 - ?)

Angie Payne, health coverage management branch administrator

Brian Pang, finance officer (1994 - ?)

Ann Kittingham, finance officer (current)

Randall Chau, systems officer (1994 – current)

Lynn Donovan, R.Ph. pharmacy consultant (1994 - current)

Kathleen Kang-Kaulupali, R.Ph.pharmacy consultant (current)

Leslie Tawata, contracts specialist supervisor (1994 – 2006)

Noreen Moon-Ng Policy & Program Development (1994 – current)

Sharon Foster, ACS PBM executive account manager, (2001 – current)

Ulka Pandya, R.Ph., ACS claims executive account manager (2001 – August 2007)

INTERROGATORY NO. 2

Identify all departments and agencies that have purchased prescription drugs for use by citizens of Hawaii, or their dependents.

ANSWER:

Objection: The defined terms improperly require Plaintiff to answer subparts or sub-questions causing the interrogatories to greatly exceed the number allowed by HRCP rule 33 and RCC rule 30(b). This question is overly broad, vague, irrelevant and not calculated to lead to any admissible evidence. This Complaint pertains only to the reimbursement by the Hawaii Medicaid Agency of drug purchasers by providers of drug benefits to Medicaid beneficiaries and certain Medicare beneficiaries.

Without waiving the objection Plaintiff responds as follows: The Office of Youth Services in the Hawaii Youth Correctional Facility; the Department of Public Safety, the Department of Health may have purchased drugs.

INTERROGATORY NO. 3

Identify all departments and agencies of Hawaii that have provided reimbursement for the cost or price of prescription drugs.

ANSWER:

Objection: The defined terms improperly require Plaintiff to answer subparts or sub-questions causing the interrogatories to greatly exceed the number allowed by HRCP rule 33 and RCC rule 30(b). This question is overly broad, vague, irrelevant and not calculated to lead to any admissible evidence. This complaint pertains only to the Hawaii Medicaid Agency.

Without waiving the objection Plaintiff responds as follows: The Department of Human Services in the Medicaid program.

INTERROGATORY NO. 4

Do you contend that any reimbursement by you for a Subject Drug that exceeds the price paid by a Provider to acquire such Subject Drug constitutes an unlawful overpayment?

ANSWER:

No.

INTERROGATORY NO. 5

If your response to Interrogatory Number 4 is anything other than an unqualified "Yes", state, as a percentage of Provider's acquisition cost, how large the "spread" or difference between the amount reimbursed by you for a Subject Drug and the price paid by a Provider to acquire such Subject Drug must be to constitute an unlawful overpayment or grounds for liability for such alleged "overpayment" by the manufacturer of that Subject Drug.

ANSWER:

Objection: The interrogatory is unintelligible. State law and federal regulations governing the reimbursement of prescription drugs in the Hawaii Medicaid Program require Hawaii to reimburse providers in excess of the price paid by the provider to the extent of the dispensing fee.

INTERROGATORY NO. 6

Identify, by Manufacturer, drug name, NDC, and quarter, the amount that you contend you overpaid for each Subject Drug as a result of each Defendants' alleged misconduct.

ANSWER:

Objection: The defined terms improperly require Plaintiff to answer subparts or sub-questions causing the interrogatories to greatly exceed the number allowed by HRCP rule 33 and RCC rule 30(b). This request is overly broad, vague, unduly burdensome, and not reasonably calculated to lead to the discovery of admissible evidence.

Without waiving the objection Plaintiff responds as follows:

Each Defendant is a manufacturer of drugs and each Defendant manufacturer maintains its own data pertaining to all of its products, by the number assigned to it under the National Drug Code, (hereafter "NDC"). As to which drugs, by NDC, are relevant to this litigation, each Defendant has been given a list of that information in the Plaintiffs Second Amended Complaint. Subject to subsequent repleading of the complaint, the Plaintiff presently contends that every drug produced by each Defendant manufacturer whose AWP it reported, or caused to be reported, that exceeded the accurate Average Wholesale Price since January 1, 1993 constituted the "misconduct" as alleged in Plaintiff's Second Amended Complaint.

The exact amount has not yet been calculated. Plaintiff is accumulating information from third parties and from Defendants that should permit these calculations. Plaintiff's mainland counsel has already shared what has been obtained with the Defendants and will produce more in response to Defendants' Document Request. The Defendants themselves have generally refused to produce such

information to Plaintiff so far. As Plaintiff receives this information for a Subject Drug, then Plaintiff can identify the amount requested by this interrogatory for each drug. The amount for a particular Subject Drug, manufactured by a particular manufacturer Defendant may be identified only to that Defendant because to do otherwise may require the disclosure of information labeled by a Defendant as "confidential" or "highly confidential" at the time it was provided to Plaintiff.

Plaintiff cannot ascertain the amount of overpayment until it obtains accurate pricing information that has been requested from Defendants in Plaintiff's outstanding discovery requests. Plaintiff will supplement its response to this interrogatory once the pricing information has been obtained and analyzed.

INTERROGATORY NO. 7

Identify the statutes, regulation, rules or other authority on which you rely to claim that Defendants had a legal duty to:

- (a) price their prescription drugs in any particular way;
- (b) refrain from discounting the prices of their prescription drugs;
- (c) refrain from confidential price negotiations concerning their prescription drugs; or,
- (c) publicly disclose the results of confidential price negotiations.

ANSWER:

Objection: The defined terms improperly require Plaintiff to answer subparts or sub-questions causing the interrogatories to greatly exceed the number allowed by HRCF rule 33 and RCC rule 30(b). This request is overly broad, vague, unduly burdensome, requires Plaintiff to conduct legal research for Defendants and not reasonably calculated to lead to the discovery of admissible evidence.

Without waiving the objection Plaintiff responds as follows: this question mischaracterizes the Plaintiff's claim, the allegations and statutes relied upon are contained in the Complaint. Defendants' "legal duty" arises from common law and the statutes alleged in the Complaint.

INTERROGATORY NO. 8

Do you contend that Defendants advertise the AWP's of their prescription drugs in any particular way? If so, please describe the basis for this contention, and list all instances of such advertisements.

ANSWER:

Objection: The defined terms improperly require Plaintiff to answer subparts or sub-questions causing the interrogatories to greatly exceed the number allowed by HRCF rule 33 and RCC rule 30(b). This request is overly broad, vague, unduly burdensome, and not reasonably calculated to lead to the discovery of admissible evidence. Defendants' have refused to provide responsive and relevant discovery relevant to this question. Plaintiff further states that other than data reflecting the prices paid by the State of Hawaii for drugs manufactured, marketed and/or distributed by Defendants, the Plaintiff is not in possession or custody of any documents that are part of Defendants' fraudulent pricing scheme. However, through work product efforts, the State's attorneys have gathered and are gathering from various outside sources documents that implicate Defendants in the pricing scheme. These documents include public information or Defendants' own records that are equally available to Defendants and their counsel. The Plaintiff's counsel should not be required at this time to marshal and produce its work product evidence obtained from outside sources.

In addition, the Defendants have not yet fully responded to the Plaintiff's longstanding discovery requests. Until further discovery is conducted and completed, the Plaintiff is not in possession of information at this time responsive to this interrogatory.

Without waiving the objection Plaintiff responds as follows: The Defendants publish their drug prices in First DataBank, Red Book or Medispan medical compendiums. The Defendants' submit an average wholesale price ("AWP"); or in some instances a price called a wholesale list price, a direct list price or a wholesale acquisition cost ("WAC") which is then marked-up by a known percentage to determine the AWP. The Defendants' represent that their drugs are for sale, and are actually sold, at the prices listed in the medical compendiums.

Defendants engage in a continuous course of business conduct that is calculated to make their false, inflated AWP prices known in the market place through their marketing efforts, primarily in printed, written and electronic materials, but also through oral communication with customers and the market generally.

The Defendants' falsely represented AWP causes the Plaintiff to over pay for drugs. This occurs every time Defendants publish, or cause the medical compendia to publish, an inflated AWP.

INTERROGATORY NO. 9

Explain in detail how you calculate the prescription drug Reimbursement rates set forth in the Hawaii Medicaid physician fee schedule, if such a fee schedule exists. If there is no such fee schedule, explain in detail how you calculate prescription drug reimbursement for physician-administered drugs.

ANSWER:

Objection: This question is burdensome, the Defendants are already in possession of this information (see Sandoz, Inc.'s Substantive Joinder in Defendant's Joint Memorandum of Law in Support of Their Motion to Dismiss, filed January 12, 2007, and Plaintiff's Opposition filed March 12, 2007) and it is public knowledge.

Without waiving the objection Plaintiff responds as follows: Documents responsive to this request will be produced but the calculation methodology is set by regulation see Haw. Admin. R. § 17-1739.1 et seq. in particular § 17-1739.1-11. In addition, this information is set forth in the State Plan. See also H.R.S. § 346-59.

Medicaid pays the estimated acquisition cost. In general Hawaii defines EAC as AWP – 10.5% plus a reasonable dispensing fee. Physicians are paid EAC plus \$0.50.

The Federal Upper Limit ("FUL") is the price established by the Center for Medicare and Medicaid Services ("CMS"). The State Maximum Allowable Cost ("MAC" or "SMAC") for multi-source drugs is the average of the estimated acquisition costs of the three least expensive generics available (one of which must be subject to rebates).

In general, for single source drugs the amount paid is calculated based upon the lesser of the billed charge, the usual and customary charge, or AWP – 10.5% plus the dispensing fee. For multiple source drugs it is calculated based upon the lesser of the billed charge, the usual and customary charge, AWP – 10.5%, the FUL price or the MAC plus a dispensing fee. The dispensing fee to pharmacies has been \$4.67 since 1989.

INTERROGATORY NO. 10

Identify all Reimbursement Methodologies that you have ever used or considered using to reimburse for physician-administered drugs under the Hawaii Medicaid Program, and the dates during which each Reimbursement Methodology was in effect, and for each Reimbursement Methodology so identified, Identify the Persons(s) most knowledgeable about each considered and implemented Methodology.

ANSWER:

Objection: The defined terms improperly require Plaintiff to answer subparts or sub-questions causing the interrogatories to greatly exceed the number allowed by HRCF rule 33 and RCC rule 30(b). This request is overly broad, vague, unduly burdensome, and not reasonably calculated to lead to the discovery of admissible evidence.

Without waiving the objection Plaintiff responds as follows: See the response to interrogatory No. 9. In 1988 doctors were paid the total ingredient cost plus \$0.50; the total ingredient cost was the estimated acquisition cost. See H.A.R. § 17-750-8 (1988) (repealed) and H.A.R. § 17-1322-11 (1992) (repealed). In 1989 Hawaii's Medicaid

started using AWP –10.5% to reduce drug costs.

In 2001, Med-Quest adopted the current reimbursement methodology, see Haw. Admin. R. § 17- 1739.1 et seq. in particular § 17-1739.1-11. EAC now is defined as AWP less 10.5% or the manufacturer's direct price as designated by the department.

Knowledgeable persons are Lynn Donovan, P.Rh. and Dr. Lynette Honbo. However, there is no current employee with knowledge of the historical (pre-1995) reimbursement methodology. Historical documents will be produced providing additional information.

INTERROGATORY NO. 11

Identify each Subject Drug the Hawaii Medicaid program reimbursed for on a basis other than on a formula derived from AWO, WAC or Direct Price; and describe the method(s) and corresponding reason(s) for this reimbursement.

ANSWER:

Objection: The defined terms improperly require Plaintiff to answer subparts or sub-questions causing the interrogatories to greatly exceed the number allowed by HRCF rule 33 and RCC rule 30(b). This request is overly broad, vague, unduly burdensome, and not reasonably calculated to lead to the discovery of admissible evidence.

Without waiving the objection Plaintiff responds as follows: Subject to interrogatory no. 9 above, and assuming "AWO" is a mistaken reference to "AWP", there is no relevant reimbursement system in Hawaii, germane to this litigation, that did not use to one extent or another the AWP's that the Defendants published or caused to be published.

For the reimbursement methodology see the response to Interrogatory 9. Certain drugs administered in hospitals or other institutions are reimbursed according to revenue codes determined by CMS and the Healthcare Common Procedure Coding System ("HCPCS"). Acute inpatient hospital claims are paid by PPS methodology. Other facilities--nursing homes, foster homes, hospitals when the patient is not acute, etc. have pharmacies that submit with NDC numbers directly to ACS PBM. Outpatient drugs are also submitted with NDC numbers except if the person is seen in the Emergency room. The information concerning reimbursement rates for individual drugs is publicly available.

INTERROGATORY NO. 12

Describe how you use or used the revised AWP's provided by the United States Department of Justice and National Association of Medicaid Fraud Control Units in 2000.

ANSWER:

Objection: The defined terms improperly require Plaintiff to answer subparts or sub-questions causing the interrogatories to greatly exceed the number allowed by HRCF rule 33 and RCC rule 30(b). This request is overly broad, vague, unduly burdensome, and not reasonably calculated to lead to the discovery of admissible evidence.

Without waiving the objection Plaintiff responds as follows: Beginning in May of 2000, the State began receiving from First DataBank revised AWP prices set by the Department of Justice for the limited number of drugs in the DOJ study. From that point in time, these prices have been considered within the State's "lowest" of reimbursement methodology.

INTERROGATORY NO. 13

Describe the methods and corresponding reasons for determining or utilizing a FUL, MAC, or SMAC for certain Subject Drugs, and Identify the Persons(s) most knowledgeable about such methods and reasons.

ANSWER:

Objection: The defined terms improperly require Plaintiff to answer subparts or sub-questions causing the interrogatories to greatly exceed the number allowed by HRCF rule 33 and RCC rule 30(b). This request is overly broad, vague, unduly burdensome, and not reasonably calculated to lead to the discovery of admissible evidence.

Without waiving the objection Plaintiff responds as follows: Each of these is a cost containment measure for multi-source drugs. The state is required by law to pay the lesser of the various charges. In general, Hawaii follows the FUL rates for multi-source drugs. In 2001, Hawaii implemented a SMAC for multiple source drugs not included in the FUL rates. Hawaii has implemented a preferred drug list and is part of the multi-state pool administered by First Health Services Corp. Hawaii also requires prior authorization for certain highly utilized, high cost medication and has quantity limits to encourage appropriate utilization. See the answer to question 9. See the First Health web site and the Med-Quest web site further information on the SMAC and preferred drug lists.

Lynn Donovan, R.Ph. pharmacy consultant, Lynette Honbo, M.D. medical consultant or Robert Coppola with First Health are familiar with these subjects.

INTERROGATORY NO. 14

For each multi-source Subject Drug, Identify the period(s) of time during which your reimbursement of that drug was based on a reported AWP and not a FUL, MAC, or SMAC.

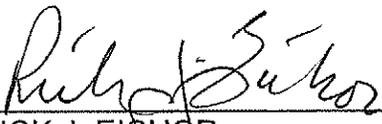
ANSWER:

Objection: The defined terms improperly require Plaintiff to answer subparts or sub-questions causing the interrogatories to greatly exceed the number allowed by HRCP rule 33 and RCC rule 30(b). This request is overly broad, vague, unduly burdensome, and not reasonably calculated to lead to the discovery of admissible evidence.

Without waiving the objection Plaintiff responds as follows: This information changes constantly, see the CMS website for historical data. Hawaii uses First DataBank for pricing and automatically updates the Medicaid formulary monthly. Subject to agreement upon the format, Plaintiff will produce claims data relevant to this question.

All objections are made by the undersigned attorney for Plaintiff.

Dated: Honolulu, Hawaii, September 4, 2007.



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