BOBBI W.Y. LUM-MEW 6299 DEPT. OF COMMERCE Regulated Industries Complaints Office CONSUMER AFFAIRS Department of Commerce and Consumer Affairs P 1: 40 State of Hawaii

Leiopapa A Kamehameha Building 235 South Beretania Street, Suite 900 HEARINGS OFFICE Honolulu, Hawaii 96813

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Attorney for Department of Commerce and Consumer Affairs

BOARD OF PHARMACY DEPARTMENT OF COMMERCE AND CONSUMER AFFAIRS STATE OF HAWAII

In the Matter of the Miscellaneous Permit of)	PHA 2010-58-L	
)		
CAREMARK ILLINOIS MAIL)	SETTLEMENT AGREEMENT PRIOR TO	
PHARMACY LLC dba CVS CAREMARK,)	FILING OF PETITION FOR DISCIPLINARY ACTION AND BOARD'S FINAL ORDER;	
Respondent.)	EXHIBIT "1"	
248040108		

SETTLEMENT AGREEMENT PRIOR TO FILING OF PETITION FOR DISCIPLINARY ACTION AND BOARD'S FINAL ORDER

Petitioner, DEPARTMENT OF COMMERCE AND CONSUMER AFFAIRS'

REGULATED INDUSTRIES COMPLAINTS OFFICE (hereinafter "RICO" or "Petitioner"),

through its undersigned attorneys, and Respondent CAREMARK ILLINOIS MAIL

PHARMACY LLC, doing business as CVS CAREMARK (hereinafter "Respondent"), enter into

this Settlement Agreement on the terms and conditions set forth below.

A. UNCONTESTED FACTS:

1. At all relevant times herein, Respondent was permitted by the Board of Pharmacy (hereinafter the "Board") as a pharmacy under Miscellaneous Permit Number PMP 419. The permit was issued on or about March 17, 2005. The permit will expire on or about December 31, 2011.

- 2. Respondent's mailing address for purposes of this action is c/o Mercedes Powers, Legal Dept., CVS Caremark, 9501 E. Shea Boulevard, MC024, Scottsdale, AZ 85260.
- 3. RICO received information that Respondent entered into a Consent Order with the Illinois Department of Financial and Professional Regulation, Division of Professional Regulation. The Consent Order indicates Respondent received three citizen complaints related to the shipping of Humalog and Novalog insulins without an accompanying cold pack. Respondent was reprimanded and agreed to pay a \$75,000.00 fine. A true and correct copy of the Consent Order with the Illinois Division of Professional Regulation in Illinois Department of Financial and Professional Regulation, Division of Professional Regulation of the State of Illinois v.

 Caremark Illinois Mail Pharmacy LLC dba CVS Caremark, License No. 054-015388 is attached as Exhibit "1."
- 4. RICO alleges Respondent did not disclose this disciplinary action to the Hawaii Board within thirty (30) days.
- 5. The foregoing allegation, if proven at an administrative hearing before the Board, would constitute violations of the following statute: Hawaii Revised Statutes ("HRS") § 436B-19(15) (disciplinary action to be disclosed within 30 days).
- 6. Respondent's previous trade name of "Caremark" was changed to "CVS Caremark"; however, Respondent did not notify the Board in a timely manner.
- 7. The foregoing allegation, if proven at an administrative hearing before the Board, would constitute violations of the following statute and/or rule: HRS § 461-21(a)(4) (violation of chapter or rules); Hawaii Administrative Rules § 16-95-21(d) (any change in information filed with the board to be reported in writing within ten days).

8. The Board has jurisdiction over the subject matter herein and over the parties hereto.

B. REPRESENTATIONS BY RESPONDENT:

- 1. Respondent is fully aware that Respondent has the right to be represented by an attorney and voluntarily waives that right.
- 2. Respondent enters into this Settlement Agreement freely, knowingly, voluntarily, and under no coercion or duress.
- 3. Respondent is aware of the right to have a hearing to adjudicate the issues in the case. Pursuant to HRS § 91-9(d), Respondent freely, knowingly, and voluntarily waives the right to a hearing and agrees to dispose of this case in accordance with the terms and conditions of this Settlement Agreement.
- 4. Respondent being at all times relevant herein permitted as a pharmacy by the Board acknowledges that Respondent is subject to penalties including but not limited to, revocation, suspension or limitation of the permit and administrative fines, if the foregoing allegations are proven at hearing.
- 5. Respondent does not admit to violating any law or rule, but acknowledges that RICO has sufficient cause to file a Petition for Disciplinary Action against Respondent's permit.
- 6. Respondent enters into this Settlement Agreement as a compromise of the claims and to conserve on the expenses of proceeding with an administrative hearing on this matter.
- 7. Respondent agrees that this Settlement Agreement is intended to resolve the issues raised in RICO's investigation in RICO Case No. PHA 2010-58-L.

- 8. Respondent understands this Settlement Agreement is public record pursuant to Hawaii Revised Statutes chapter 92F.
- 9. Respondent submits that it immediately corrected the situation with its name change as soon as RICO brought this matter to its attention.

C. TERMS OF SETTLEMENT:

- 1. Administrative fine. Respondent agrees to pay a fine in the amount of ONE THOUSAND AND NO/100 DOLLARS (\$1,000.00). Payment shall be made by cashier's check or money order made payable to "DCCA Compliance Resolution Fund" and mailed to the Regulated Industries Complaints Office, Attn: Bobbi W.Y. Lum-Mew, Esq., 235 S. Beretania Street, 9th Floor, Honolulu, Hawaii 96813. Payment of the fine shall be due at the time this fully executed Settlement Agreement is returned to RICO.
- 2. Failure to Comply with Settlement Agreement. If Respondent fails to fully and timely comply with the terms of this Settlement Agreement as set forth in paragraph(s) C.1 above, Respondent's permit shall be automatically revoked upon RICO's filing of an affidavit with the Board attesting to such failure. In case of such revocation, Respondent shall turn in all indicia of the permit to the Executive Officer of the Board within ten (10) days after receipt of notice of the revocation. In case of such revocation, Respondent understands Respondent cannot apply for a new permit until the expiration of at least five (5) years after the effective date of the revocation. Respondent understands that if Respondent desires to become permitted again, Respondent must apply to the Board for a new permit pursuant to and subject to HRS §§ 92-17, 436B-21, and all other applicable laws and rules in effect at the time.

- 3. <u>Possible further sanction</u>. The Board, at its discretion, may pursue additional disciplinary action as provided by law to include further fines and other sanctions as the Board may deem appropriate if Respondent violates any provision of the statutes or rules governing the conduct of pharmacies in the State of Hawaii, or if Respondent fails to abide by the terms of this Settlement Agreement.
- 4. <u>Approval of the Board</u>. Respondent agrees that, except for the representations, agreements and covenants contained in Paragraphs C.5, C.6, C.7 and C.8 below, this Settlement Agreement shall not be binding on any of the parties unless and until it is approved by the Board.
- 5. No Objection if Board Fails to Approve. If the Board does not approve this

 Settlement Agreement, does not issue an order pursuant thereto, or does not approve a lesser remedy, but instead an administrative hearing is conducted against Respondent in the Board's usual and customary fashion pursuant to the Administrative Procedure Act, Respondent agrees that neither Respondent nor any attorney that Respondent may retain, will raise as an objection in any administrative proceeding or in any judicial action, to the Board's proceeding against Respondent on the basis that the Board has become disqualified to consider the case because of its review and consideration of this Settlement Agreement.
- 6. <u>Any Ambiguities Shall be Construed to Protect the Consuming Public</u>. It is agreed that any ambiguity in this Settlement Agreement is to be read in the manner that most completely protects the interests of the consuming public.
- 7. No Reliance on Representations by RICO. Other than the matters specifically stated in this Settlement Agreement, neither RICO nor anyone acting on its behalf has made any representation of fact, opinion or promise to Respondent to induce entry into this Settlement

Agreement, and Respondent is not relying upon any statement, representation or opinion or promise made by RICO or any of its agents, employees, representatives or attorneys concerning the nature, extent or duration of exposure to legal liability arising from the subject matter of this Settlement Agreement or concerning any other matter.

8. <u>Complete Agreement</u>. This Settlement Agreement is a complete settlement of the rights, responsibilities and liabilities of the parties hereto with respect to the subject matter hereof; contains the entire agreement of the parties; and may only be modified, changed or amended by written instrument duly executed by all parties hereto.

IN WITNESS WHEREOF, the parties have signed this Settlement Agreement on the date(s) set forth below.

DATED: Mt. Prospect, Illinois, 2-9-2011 (CITY) (STATE), 2-9-2011 (DATE).

CAREMARK ILLINOIS MAIL PHARMACY LLC

DATED: Honolulu, Hawaii, _____

DARIA A. LOX-GOTO
BOBBI W.Y. LUM-MEW
Attorneys for Department of Commerce and Consumer Affairs

IN THE MATTER OF THE MISCELLANEOUS PERMIT OF CAREMARK ILLINOIS MAIL PHARMACY LLC DBA CVS CAREMARK; SETTLEMENT AGREEMENT PRIOR TO FILING OF PETITION FOR DISCIPLINARY ACTION AND BOARD'S FINAL ORDER; CASE NO. PHA 2010-58-L; EXHIBIT "1"

APPROVED AND SO ORDERED: BOARD OF PHARMACY STATE OF HAWAII

MARK E. BROWN

Chairperson

PATRICK ADAMS

Vice Chairperson

CARRETT A. LAU

STANIEV M CHOW

PVL 09/01/10

April 21, 2011

TODD INAFUKU

KARL H. MIYAMOTO

ELIZABETH C. HC

STATE OF Illinois)
COUNTY OF COOK) SS.)
On this 7th day of Cel	
appeared Jason Perry, to me kr	nown to be the person described, and who executed
the foregoing instrument on behalf of Care	nark Illinois Mail Pharmacyas L. L. C.
Automotion & S	cknowledged that he/she executed the same as
his/her free act and deed.)
Official Seal Karen Riden Notary Public State of Illinois My Commission Expires 05/09/2012	Karen Riden Kaien Reden Name: Notary Public, State of Ellinois My Commission expires: 5/9/2012

STATE OF ILLINOIS

ILLINOIS DEPARTMENT OF FINANCIAL AND PROFESSIONAL REGULATION DIVISION OF PROFESSIONAL REGULATION

ILLINOIS DEPARTMENT OF FI REGULATION, DIVISION OF P	NANCIAL AND PROFESSIONAL ROFESSIONAL REGULATION)
of the State of Illinois,	Complainant	ĺ
v,) No. 2009-05339
CAREMARK ILLINOIS MAIL P	HARMACY LLC	<i>)</i>
d/b/a CVS CAREMARK)
License No. 054-015388,	Respondent)

CONSENT ORDER

The Illinois Department of Financial and Professional Regulation, Division of Professional Regulation (hereinafter the "Department") by Scott A. Golden, its attorney, and CAREMARK ILLINOIS MAIL PHARMACY LLC, d/b/a CVS CAREMARK, Respondent, agree to the following:

STIPULATIONS

CAREMARK ILLINOIS MAIL PHARMACY LLC, d/b/a CVS CAREMARK, is licensed as a pharmacy in the State of Illinois, holding license No. 054-015388. Said license is presently in active status. At all times material to the matters set forth in this Consent Order, the Illinois Department of Financial and Professional Regulation had jurisdiction over the subject matter and parties to this Consent Order.

The Department received three (3) citizen complaints related to the shipping of Humalog and Novolog insulins by CAREMARK ILLINOIS MAIL PHARMACY LLC, d/b/a CVS CAREMARK. Specifically, the citizen complainants stated that they received shipments of the aforementioned insulins without an accompanying cold pack. Manufacturer's standards for Humalog and Novolog insulins dictate that the medication should be stored at a temperature

between 2° and 8°C (36° and 46°F) until opened.

If these allegations were proven at a hearing to be true, then these allegations would constitute grounds for discipline of Respondent's license as a pharmacy in the State of Illinois on the authority of 225 ILCS 85/30(a)(2); Ill. Admin. Code tit. 68, § 1330.80(b)(1); 410 ILCS 620/3; and 410 ILCS 620/3.1.

As a result of these allegations, the Department held an Informal Disciplinary Conference at the offices of the Department, 100 West Randolph Street, Suite 9-300, in Chicago, Illinois, on July 22, 2009. Respondent, by its designated representatives, appeared on that date, represented also by counsel, Barry A. Jasilli, R.Ph., J.D. and Amy R. Cotton, J.D. Robert J. Anselmo, R.Ph. appeared as a member of the Illinois State Board of Pharmacy, and Scott A. Golden appeared as the attorney for the Department.

Respondent has fully cooperated with the Department in this matter. Respondent neither admits nor denies the conclusions that form the basis of this Consent Order and presents the following in mitigation: Respondent states that the pharmacy's method of shipping Humalog and Novolog insulins is supported by clinical information from the Veteran's Administration study, "Insulin Temperature and Stability under Simulated Transit Conditions" by Dr. C. Chandler. Additionally, the pharmacy relied on a second study published by Diabetes Care in September of 2003, "How Long Should Insulin Be Used Once A Vial is Started" by Dr. M. Grajower. Respondent states that the pharmacy's method for shipping the insulins at issue was designed to maintain the integrity of the insulin during shipment. Further, Respondent states that no patient harm resulted from said shipping method.

Respondent has been advised of the right to have the pending allegation reduced to written charges, the right to a hearing, the right to contest any charges brought, and the right to

administrative review of any Order resulting from a hearing. Respondent knowingly waive each of these rights, as well as any right to administrative review of this Consent Order. Such waiver ceases if this Consent Order is rejected by either Illinois State Board of Pharmacy or the Director of the Division of Professional Regulation of the Illinois Department of Financial and Professional Regulation. Respondent acknowledges that it has entered into this Consent Order freely and of its own will without threat or coercion by the Department or any person. Respondent acknowledges that the Department attorney may be requested to communicate with the Illinois State Board of Pharmacy or the Director of the Division of Professional Regulation of the Illinois Department of Financial and Professional Regulation in furtherance of the approval of this Consent Order.

Respondent and the Department have agreed, in order to resolve this matter, that Respondent be permitted to enter into a Consent Order with the Department, providing for the imposition of disciplinary measures which are fair and equitable in these circumstances and which are consistent with the best interests of the people of the State of Illinois.

CONDITIONS

WHEREFORE, the Illinois Department of Financial and Professional Regulation, Division of Professional Regulation through Scott A. Golden, its attorney, and CAREMARK ILLINOIS MAIL PHARMACY LLC, d/b/a CVS CAREMARK, Respondent, agree:

- A. The license of CAREMARK ILLINOIS MAIL PHARMACY LLC, d/b/a CVS CAREMARK, License No. 054-015388, to practice as a pharmacy in the State of Illinois is REPRIMANDED.
- B. Respondent CAREMARK ILLINOIS MAIL PHARMACY LLC, d/b/a CVS CAREMARK, shall pay a seventy-five thousand and no/100 dollar (\$75,000.00) fine within sixty (60) days of the effective date of this Order. The fine is to be paid by

personal check, cashiers check, or personal money order. Said check shall be made payable to:

Illinois Department of Financial and Professional Regulation Attention: Fiscal Section 320 W. Washington, 3rd floor Springfield, IL 62786.

In the notation portion of the check, case No. 2009-05339, and the license No. 054-015388 shall be reflected.

- C. If Respondent CAREMARK ILLINOIS MAIL PHARMACY LLC, d/b/a CVS CAREMARK, fails to pay the aforementioned fine and the Department initiates a collection effort to retrieve the fine, Respondent CAREMARK ILLINOIS MAIL PHARMACY LLC, d/b/a CVS CAREMARK, shall be responsible for all costs and fees incurred by the Department in said collection effort.
- D. Any violation by Respondent of the terms and/or conditions of this Consent Order shall be grounds for the Department to immediately file a Complaint to revoke or otherwise discipline Respondent's license to practice as a pharmacy in the State of Illinois.
- E. This Consent Order shall become effective immediately upon signing and approval by the Director of the Division of Professional Regulation of the Illinois Department of Financial and Professional Regulation.

DIVISION OF PROFESSIONAL REGULATION

	of the State of Illinois
12/8/09	Lim 2
DATE	Scott A. Golden
	Attorney for the Department
	Will Allenger
DATE	
DATE	Caremark Illinois Mail Pharmacy LLC, d/b/a CVS
	Caremark, by its designated representative, Respondent
	by its designated representative, Kespondent
The Access	130000 2 - Spain St
DATE	Barry A. Jasñli, R.Ph., J.D.
(A) () () () () () () () () ()	Attorney for Respondent
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DATE	Robert J. Anselmo, R.Ph.
	Member, Board of Pharmacy
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THIS CONSENT ORDER IS APPRO	OVED IN FULL:
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DATED THISDAY	OF
	ILLINOIS DÉPARTMENT OF FINANCIAL AND
	PROFESSIONAL REGULATION
	OF THE STATE OF ILLINOIS
	BRENT E. ADAMS, SECRETARY DEVISION OF PROFESSIONAL DECEM ATION
	DIVISION OF PROFESSIONAL REGULATION
	DANIEL E. BLUTHARDT
	DANIEL E. BLUTHARDT

Case Nos. 2009-05339 License Nos. 054-015388 DIRECTOR