



INVOICE and PURCHASE AGREEMENT for BabyBIG®

Patient Name _____ **Invoice Number** _____
 _____ (to be obtained from IBTPP)
Hospital Name _____ **Hospital P.O. Number** _____
 _____ (if assigned)
City, State _____ **Date** _____

Patient weight in kilograms at the time of order (vials needed based on weight) _____

GENERAL INSTRUCTIONS for PHARMACY

1. If possible, obtain an institutional Purchase Order Number (usually issued by the Pharmacy Department) and enter it in the above space. A PO number is for the internal tracking purposes at the ordering facility; *note that this page is the invoice for this order, a separate invoice will not be issued.*
2. **Obtain the duly authorized institutional signatures on page 7 of this Agreement.** Make a copy of the signed Invoice and Purchase Agreement (IPA) for delivery to your institution's Accounts Payable department as soon as possible, as payment is due within five (5) business days.
Fax the IPA to the Infant Botulism Treatment and Prevention Program (IBTPP) at (916) 636-6242 or (855) 506-6566 (toll free).
3. **Hand-deliver the copy of the IPA to your hospital's Accounts Payable department ASAP** for completing the wire transfer of funds. Payment is required within five (5) business days.
4. Return the IPA with original signatures to IBTPP by mail.
5. **Please note that your hospital is responsible for collecting and submitting a diagnostic stool/enema specimen(s) (see p. 4).**

***** INVOICE *****

BabyBIG® FEE for the treatment of the above-named patient:..... **US\$45,300--**

1. Name of Bank: **Bank of America, Sacramento, CA**
2. Name of Account/Pay to: **CA Department of Public Health, BabyBIG® Fund 0272**
3. Bank Account Number: **14364-80640** (please use the dash)
4. Wire Transfer Instructions: **Wire Transfer payment ABA Number: 026009593**
 SWIFT #: BOFAUS3N *We cannot accept checks; do not send a check.*
5. **Invoice # _____ - Deposit to BabyBIG® Fund 0272.**

Due Date: within five (5) business days from the date of this document as written above, in order to avoid liability for late penalties (see p. 2, paragraph 1, and p. 6, paragraphs 12 and 13).

INFORMATION and INSTRUCTIONS for Accounts Payable Department:

- If unable to do so directly, funds should be wired from your institution's regular bank.
- Remittance information must include the full invoice number/information as on line 5 above.

The payment information and account above are to be used exclusively for BabyBIG® fees. The IBTPP does not have a W-9 form distinct from CDPH; it is the responsibility of the Hospital/Purchaser to be certain that no vendor accounts are created in a manner that will cause inappropriate payments into this account.

If you have questions about this agreement or invoice, please contact the Regulatory Manager or Health Program Specialist at the CDPH Infant Botulism Treatment and Prevention Program at (510) 231-7600.

PURCHASE AGREEMENT FOR BabyBIG®
[Botulism Immune Globulin Intravenous (Human)]

This Agreement (Agreement) is made and entered into this ____ day of _____, 20 ____ by and between the State of California, through its duly elected or appointed, qualified and acting officer Katya Ledin, Ph.D., M.P.H., Chief, Infectious Diseases Laboratory Branch, California Department of Public Health, with a principal place of business located at 850 Marina Bay Parkway, Bldg E, Richmond, CA 94804, acting for the **California Department of Public Health Infant Botulism Treatment and Prevention Program**, which has its principal place of business located at **850 Marina Bay Parkway, Room E-361, Richmond, California 94804**, and the _____ (Hospital/Medical Center), with a principal place of business located at _____, hereafter called the Purchaser.

Recitals:

1. Whereas, in 1989 the California Department of Public Health (CDPH) in a Cooperative Agreement with the U.S. Food and Drug Administration (FDA) undertook the development and testing of Botulism Immune Globulin Intravenous (Human) (BIG-IV) for the treatment of the orphan disease of infant botulism; and,
2. Whereas, BIG-IV was designated by FDA in 1989 to be an Orphan Drug that is sponsored by CDPH; and,
3. Whereas, CDPH conducted a randomized, double-masked, placebo-controlled, statewide pivotal clinical trial between 1992 and 1997, which demonstrated that BIG-IV is safe and effective for the treatment of infant botulism by reducing average hospital stay and average hospital costs by more than 55% each; and,
4. Whereas, CDPH extended the pivotal clinical trial results with a nationwide "open-label" study between 1998 and 2003, which demonstrated that BIG-IV shortened average hospital stay from 5.7 weeks to 2.2 weeks and reduced average hospital costs from \$207,500 to \$72,900 *per patient* (costs adjusted to 2015 dollars); and
5. Whereas, on 23 October 2003 FDA licensed BIG-IV as BabyBIG® for the treatment of infant botulism types A and B; and,
6. Whereas, California Health & Safety Code Sections 123700-123709 established the Infant Botulism Treatment and Prevention Program (IBTPP) within CDPH for the purposes of a) assuring the on-going availability of a national supply of BabyBIG®, b) providing statewide diagnostic and consultative services for infant botulism, and c) reducing the occurrence of infant botulism and related illnesses in California; and,
7. Whereas, California Health & Safety Code Section 123704 requires the IBTPP to distribute BabyBIG® in California and nationwide to patients suspected of having infant botulism in accord with federal law; and,
8. Whereas, federal law authorizes and State law requires that CDPH as Sponsor of BabyBIG® charge a fee in exchange for BabyBIG® in order to meet but not exceed the IBTPP operational expenses, including the developmental and on-going production costs of BabyBIG®; and,
9. Whereas, State law mandates that IBTPP investigate ways to improve the treatment of infant botulism, including making technical improvements to BabyBIG®, and develop and implement control measures for the prevention of infant botulism and related illnesses; and,

10. Whereas, federal law [21CFR314.80(c)(2) and 21CFR314.81(b)(2)] requires CDPH as the Sponsor of BabyBIG® to collect specified information, and federal law also authorizes hospitals to release patient "protected health information" without obtaining the subject's consent to the sponsor of a licensed medical product [45CFR164.512(b)(1)(iii)]; and,
11. Whereas, CDPH as the Sponsor of BabyBIG® is required to provide such information to FDA to comply with licensure maintenance requirements for BabyBIG®; and,

WHEREAS, _____ Hospital has admitted a patient whom it believes has infant botulism and wishes to procure BabyBIG® for the treatment of this patient;

NOW, THEREFORE, in consideration of the mutual covenants, conditions, agreements, and stipulations contained herein, and with the intent to be legally bound thereby, the parties do agree as follows:

Terms and Payment:

1. a. Purchaser agrees to pay to CDPH/IBTPP in cash by **Wire Transfer only** a fee of \$ 45,300.00 (Forty Five Thousand Three Hundred DOLLARS) for the BabyBIG® needed to treat this patient.
- b. **Purchaser agrees that the fee for BabyBIG® is the retail price for this product and agrees not to add any mark-ups to this price in order to collect fees in greater amounts when billing third parties for BabyBIG®.**
- c. Payment must be received within **five (5) business days** of signing this agreement.
- d. The **invoice number** for this transaction is _____.
(obtain from IBTPP)
- e. The fee wire transfer instructions are as follows: a) Name of Bank: Bank of America, Sacramento, CA, b) Account Name: California Department of Public Health BabyBIG® Fund 0272, c) Bank Account Number: 14364-80640, d) Wire-transfer ABA #: 026009593; ACH ABA #: 121000358; Swift # BOFAUS3N
- f. **Must include on transfer: "Deposit to _____ BabyBIG®/Fund 0272."**
(obtain from IBTPP)
- g. Hospital P.O. number, if known: _____.

[For any difficulties encountered in using these instructions, please contact the CDPH/IBTPP Program Administrator at (510) 231-7600 (telephone) or the Accounting Administrator, California Department of Public Health, at (916) 322-1406 (telephone).]

2. **For non-U.S. cases only**, Purchaser shall send an appropriate packaged stool/enema specimen(s) to the CDPH IBTPP laboratory for diagnostic studies.

Request for BabyBIG®

3. Purchaser agrees to designate an attending staff physician for this patient. Purchaser shall require the attending staff physician to provide the following information to the IBTPP, as authorized by 45 CFR 164.512(b)(1)(iii):
 - a. Date and time of notification of public health officials of this case of possible infant botulism and of the specific arrangements made for diagnostic testing of fecal and/or enema specimen(s) for the mandatory establishment of the diagnosis of infant botulism, and
 - b. Additional information as specified in paragraphs 4, 5 and 6 of this Agreement to enable the IBTPP to investigate ways to improve the treatment of infant botulism.
4. Purchaser agrees to provide the following information and documents by electronic transfer (fax) at the time of its written request (i.e., the duly-signed Invoice and Purchase Agreement) for BabyBIG®:
 - a. Name, address, telephone number and date of birth of the patient to be treated with BabyBIG®.
 - b. Name, address and telephone number of parent(s) or guardian(s) of the patient to be treated with BabyBIG®.
 - c. Date(s) of admission to Purchaser's hospital and of admission to any hospital for the present illness that is considered to be probable infant botulism.
 - d. Admission diagnosis or diagnoses.
 - e. Hospital record number.
 - f. Name, address, business telephone and fax number of patient's attending physician.
 - g. Patient's admission history, physical examination findings, and results of laboratory and diagnostic studies.
 - h. Treatment plan and medications prescribed, or equivalent document.
5. Purchaser agrees to provide the following information to CDPH/IBTPP after administration of BabyBIG® to patient and within 24 hours of the occurrence or the recognition of occurrence:
 - a. Any adverse reaction in the patient treated with BabyBIG®, either suspected or actual, that occurs within 5 days of administration of BabyBIG®.
 - b. The circumstances under which any adverse reaction, either suspected or actual, occurred within 5 days of administration of BabyBIG®.
 - c. The reasons why the reaction may or may not have been related to the administration of BabyBIG® to the patient.
 - d. The transmission, or possible transmission, of any virus or other transmissible etiological agent to the patient due to administration of BabyBIG®.

6. Purchaser agrees to provide the following information at no charge to CDPH/IBTPP within two weeks after the patient treated with BabyBIG[®] has been discharged from the hospital:
 - a. Admission and discharge summaries, and other medical record information if requested, e.g., nurses' notes, medication records, etc.
 - b. A listing of hospital charges, costs, and reimbursements for the patient's hospital stay.

Delivery of BabyBIG[®]

7. Upon receipt by facsimile (fax) of this executed Agreement by Purchaser, together with the information listed in Paragraph 4, CDPH/IBTPP agrees to provide and promptly ship by an expedited courier known to CDPH to be qualified for this purpose to the Purchaser the BabyBIG[®] needed to treat this patient. **For non-United States patients, the shipping costs, handling fees, and customs charges, if any, for BabyBIG[®] are the responsibility of the hospital. Arrangements for billing these charges to the hospital must be made in advance of shipment. CDPH reserves the right to approve or disapprove any proposed alternative courier or third-party intermediary involved in the transport of BabyBIG[®] to the hospital.**

Liability

8. Purchaser shall be liable for loss or damage of BabyBIG[®] which occurs in transit or after transit subsequent to delivery of BabyBIG[®] to the transporting courier. BabyBIG[®] becomes the property of the hospital at this point.

Indemnification

9. Purchaser agrees to indemnify, defend and hold harmless the CDPH, its officers, agents, and employees from any and all liability, demands, claims, costs, losses, damages, recoveries, settlements, and expenses (including interest, penalties, attorney fees, accounting fees, and expert witness fees) incurred by Purchaser accruing or resulting to any person, firm or corporation who may be injured or damaged by the Purchaser as a result of Purchaser's action or inaction in the performance of this Agreement.
10. CDPH/IBTPP warrants that BabyBIG[®] will conform to the specifications and descriptions incorporated herein. **IBTPP MAKES NO OTHER WARRANTY, EXPRESS OR IMPLIED, AND SPECIFICALLY MAKES NO WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE OTHER THAN THE PURPOSES DETAILED IN THE SPECIFICATIONS AND DESCRIPTION IN THE U.S. FDA-APPROVED PACKAGE INSERT FOR BabyBIG[®].**

Remedies for Breach

11. All parties recognize and agree that information related to treatment with BabyBIG[®] and the rights and obligations set forth in this Agreement are unique and are of such a nature as to be inherently difficult or impossible to value monetarily. Therefore, in the event of a breach of this Agreement by any party, an action at law for damages or other remedies at law would be inadequate to protect the unique rights and interests of the parties to this Agreement. Accordingly, in any controversy concerning the purchase, sale,

or shipment of BabyBIG[®] or of any of the terms of this Agreement, its provisions shall be enforceable by specific performance. This remedy shall not be exclusive and shall be in addition to any other remedy available to the parties.

12. Purchaser acknowledges that IBTPP is relying on Purchaser to deliver the fee for BabyBIG[®] described in Paragraph 1 and the information described in Paragraphs 4, 5 and 6 within the time indicated in the terms of this Agreement. If Purchaser fails to deliver the fee or provide any item of information in accordance with the terms of this Agreement, Purchaser shall pay to IBTPP as liquidated damages and not as a penalty the amount of \$300.00 (Three Hundred DOLLARS) per day for each day delivery is delayed beyond the scheduled date.

Miscellaneous

13. Without the written consent of the CDPH/IBTPP, this Agreement is not assignable by Purchaser either in whole or in part.
14. This Agreement constitutes a valid and binding obligation on each party, enforceable in accordance with its terms.
15. No consent or approval of any other person or governmental authority is necessary for this Agreement to be effective.
16. This Agreement constitutes the full understanding of the parties and a complete and exclusive statement of the terms of the Agreement.
17. This Agreement shall be governed by and construed in accordance with the laws of California.
18. Whenever possible, each provision of the Agreement shall be interpreted in such manner as to be effective and valid under applicable law, but if any provision of the Agreement shall be prohibited by or invalid under applicable law, such provision shall be ineffective to the extent of such prohibition or invalidity, without invalidating the remainder of such provision or the remaining provisions of the Agreement.
19. No amendment of the terms of this Agreement shall be valid unless made in writing and signed by the parties hereto, and no oral understanding or agreement not incorporated herein, shall be binding on any of the parties hereto.

AUTHORIZED OFFICIAL OF THE PURCHASING INSTITUTION (INTERNATIONAL CASES):

Institution Responsible for Payment

Signature of Authorized Official; Date

Street Address

Printed Name of Authorized Official

City, State or Province, Country

Title of Authorized Official

Telephone Number of Authorized Official

Email of Authorized Official

Name of Patient's Hospital

Signature of Hospital CFO or CEO; Date

Telephone # of Hospital CFO or CEO

Printed Name of Hospital CFO or CEO

Contact person in Accounts Payable Department of the Purchasing Institution to whom the Authorized Official will promptly deliver a copy of this Agreement:

Name (Accounts Payable Contact)


Fax Number for Accounts Payable Contact

Title (Accounts Payable Contact)

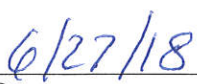
Email for Accounts Payable Contact

Phone Number for Accounts Payable Dept.

AUTHORIZED OFFICIAL OF THE CALIFORNIA DEPARTMENT OF PUBLIC HEALTH:



Katya Ledin, Ph.D., M.P.H., Chief
Infectious Diseases Laboratory Branch



Date