

## INTERIM MONITOR AGREEMENT

*October* This Interim Monitor Agreement (Monitor Agreement) entered into as of this *5th* day of ~~August~~, 2006 by and among F. William Rahe, an individual (Rahe) and Barr Pharmaceuticals, Inc. (Barr or Respondent) provides as follows:

WHEREAS, the United States Federal Trade Commission (the Commission) has approved a Decision and Order (Order) with Barr, which, among other things, requires Respondents to license or transfer certain defined assets and maintain those assets pending such license or transfer, and provided for the appointment of an Interim Monitor to ensure that Respondents comply with their obligations under the Order;

WHEREAS, the Commission may appoint Rahe as such monitor (the Interim Monitor) pursuant to the Order to monitor Respondents' compliance with the terms of the Consent Agreement and Order and with the Remedial Agreements referenced in the Order, and to monitor the efforts of the Commission-approved Acquirer (as defined in the Order) to obtain all necessary FDA approvals, as applicable, and Rahe has consented to such appointment;

WHEREAS, the Order further provides or will provide that Respondents shall execute a Monitor Agreement, subject to the prior approval of the Commission, conferring all the rights, powers and authority necessary to permit the Interim Monitor to carry out such duties and responsibilities pursuant to the Order;

WHEREAS, this Monitor Agreement conforms with the requirements of the Order and does not contradict the Order;

WHEREAS, this Monitor Agreement, although subject to Commission approval, is effective for any purpose, including but not limited to imposing rights and responsibilities on Respondents or the Interim Monitor under the Order, upon execution by the parties; and

WHEREAS, the parties to this Monitor Agreement intend to be legally bound;

NOW, THEREFORE, the parties agree as follows:

1. Capitalized terms used herein and not specifically defined herein shall have the respective definitions given to them in the Consent Agreement and the Order. The term Monitored Assets means the Categorized Assets as defined in the Consent Agreement.
2. The Interim Monitor shall have all of the powers, responsibilities and protections conferred upon the Interim Monitor by the Order. The Order is hereby attached as Exhibit A to this Monitor Agreement, the terms of which are incorporated herein by reference.

3. Respondents hereby agree that, upon execution by both parties of this Monitor Agreement, Respondents will fully comply with all terms of the Order requiring them to confer all rights, powers, authority and privileges upon the Interim Monitor, or to impose upon themselves any duties or obligations with respect to the Interim Monitor, to enable the Interim Monitor to perform the duties and responsibilities of the Interim Monitor thereunder.
4. Respondents further agree that:
  - a. they will use their best efforts to ensure that any Commission-approved Acquirer that is acquiring or licensing assets pursuant to Paragraphs II and III of the Decision and Order (or as otherwise specified by the Commission) enters into an appropriate agreement with the Interim Monitor as soon as practicable after the execution of this Monitor Agreement;
  - b. no later than ten (10) Business Days after the Commission approves this Monitor Agreement, they will provide the Interim Monitor with:
    - (1) a complete description of the Monitored Assets, identifying, in particular, those Monitored Assets which may require actions to maintain their viability and marketability, and the person(s) responsible for taking those actions;
    - (2) a complete inventory of all existing FDA approvals and pending FDA approvals for the Products included in the Monitored Assets identifying actions required to maintain or complete such approvals and identifying the person(s) responsible for taking such actions;
    - (3) a complete inventory of all activities or operations worldwide that relate to the manufacture of the Products relating to the Monitored Assets, and which relate to Respondents' compliance with the Order, including processes and process validations which are under development, identifying the person(s) responsible for maintaining or pursuing such activities and giving an inventory of materials and records relating to such manufacture; and
    - (4) a complete inventory of all Patents included in the Monitored Assets related to the manufacture or sale of the Monitored Assets in the United States, identifying actions needed to maintain such Patents and the person(s) responsible for such actions;

- c. they will designate a senior individual as a primary contact for the Interim Monitor and provide a written list of the principal individuals involved in the licensing of the Monitored Assets to the Commission-approved Acquirer, together with their location, telephone numbers, electronic mail address (if available), and responsibilities, and will provide the Interim Monitor with written notice of any changes in such personnel occurring thereafter;
- d. they will provide the Interim Monitor with prompt notification of significant meetings, including date, time and venue, scheduled after the execution of this Monitor Agreement, relating to the development, manufacture, registration, regulatory approvals, marketing, sale and divestiture of the Monitored Assets, and such meetings may be attended by the Interim Monitor or its representative, at the Interim Monitor's option or at the request of the Commission or staff of the Commission;
- e. they will provide the Interim Monitor the minutes of the above-referenced meetings as soon as practicable and, in any event, not later than those minutes are available to any employee of the Respondents;
- f. they will provide the Interim Monitor with all correspondence, meeting minutes, reports, sent to or received from the FDA relating to the Monitored Assets;
- g. they will provide the Interim Monitor with electronic or hard copies, as may be appropriate, of all reports submitted to the Commission pursuant to the Consent Agreement and the Order, simultaneous with the submission of such reports to the Commission;
- h. to the extent not reflected in the reports submitted to the Commission pursuant to the Consent Agreement and the Order, they will provide every (3) months commencing one (1) month after the Consent Agreement is accepted by the Commission for public comment, or as requested by the Interim Monitor, full and detailed electronic or hard copy reports to the Interim Monitor as to all of Respondents' activities and obligations under the Order concerning the Monitored Assets including, without limitation to the extent applicable:
  - (1) all activities involving the research and development, pre-clinical and clinical studies and pursuit and maintenance of FDA clearance or approvals relating to the Monitored Assets;

- (2) all activities concerned with the licensing, manufacture, supply and technology transfer of the relevant Products that are identified in the Monitored Assets, including, without limitation, negotiation and operation of supply agreements, actual supply and inventory;
- (3) all minutes and records of meetings, action plans, and follow-ups to actions plans and meetings, with the Commission-approved Acquirers related to the licensing, manufacture, supply, and technology transfer of the Products identified in the Monitored Assets;
- (4) all activities concerning the assistance, advice and consultation provided to any Commission-approved Acquirer generally as provided in Paragraph II of the Decision and Order; and
- (5) on request, Respondents will provide the Interim Monitor with any and all records that relate to the licensing and manufacture of the Products identified in the Monitored Assets with the right to use them to achieve the purpose of the Order;

*provided, however, that, at the time the Decision and Order becomes final, the reports described in this paragraph together with all other information and documents referred to herein shall be due to the Interim Monitor either as requested by the Interim Monitor or within five (5) Business Days of the date that Respondents file the Respondents' reports with the Commission as required pursuant to Paragraph V and VI of the Decision and Order;*

- i. they will comply with the Interim Monitor's requests for onsite visits and audits of Respondents' facilities used to manufacture the Products identified in the Monitored Assets;
- j. they will comply with the Interim Monitor's requests for follow-up discussions or supplementary information concerning any reports provided to or requested by the Interim Monitor pursuant to this Agreement or in connection with any matters the Interim Monitor deems reasonably necessary to perform its responsibilities under the Order, including, without limitation, meetings and discussions with the principal staff involved in any activities relating to the research, development, manufacture, sale, licensing, and/or divestiture of the Monitored Assets or any Product comprised therein and, further including, actions necessary to maintain all necessary FDA or other foreign regulatory agency equivalent approvals to manufacture and sell any of the Monitored Assets, to

maintain the viability and marketability of the Monitored Assets, as well as the tangible assets of the facilities used to manufacture and sell all of the Monitored Assets, and to prevent the destruction, removal, wasting, deterioration or impairment of the Monitored Assets, and will provide the Interim Monitor with access to and hard and electronic copies of all other data, records or other information that the Interim Monitor believes are necessary to the proper discharge of its responsibilities under the Order;

- k. they will provide prompt notice of any meetings, activities or events affecting or likely to affect the maintenance of the Monitored Assets including, but not limited to, any and all meetings or communications with the FDA; and
  - l. they will provide the Interim Monitor with such other information, documents and the like requested by the Interim Monitor in order to carry out its responsibilities under this Monitoring Agreement.
5. Respondents shall promptly notify the Interim Monitor of any significant written or oral communication that occurs after the date of this Monitor Agreement between the Commission and Respondents related to the Order or this Monitor Agreement, together with electronic or hard copies (or, in the case of oral communications, summaries), as may be requested by the Interim Monitor, of such communications.
  6. Respondents agree that, to the extent authorized by the Order, the Interim Monitor shall have the authority to employ, at the expense of the Respondents, such consultants, accountants, attorneys and other representatives and assistants as are reasonably necessary to carry out the Interim Monitor's duties and responsibilities, including but not limited to supervising the transfer of Confidential Business Information related to the Product Manufacturing Technology, Product Scientific and Regulatory Material, and Product Trademarks, as defined in the Order, related to the Monitored Assets.
  7. Respondents and the Interim Monitor understand and agree that the Commission or its staff may request, pursuant to and consistent with the Order, that the Interim Monitor investigate and/or audit the Respondents' compliance with the Respondents' obligations to maintain assets pursuant to the Order, and submit such additional written or oral reports, under applicable confidentiality restrictions, to the Commission as the Commission or its staff may at any time request concerning the Respondents' compliance with the Respondents' obligations to maintain assets pursuant to the Order.
  8. The Interim Monitor shall maintain the confidentiality of all information provided to the Interim Monitor by Respondents. Such information shall be used by the Interim Monitor only in connection with the performance of the Interim Monitor's

duties pursuant to this Agreement. Such information shall not be disclosed by the Interim Monitor to any third party other than:

- a. persons engaged or employed by, or working with, the Interim Monitor under this Monitor Agreement;
- b. any Commission approved Acquirer to the extent that the information is of a non-privileged nature and relates to the Monitored Assets; or
- c. persons employed at or by the Commission and working on this matter.

Notwithstanding anything herein to the contrary, Respondents shall use their best efforts to identify and/or label such information in writing they desire to treat as privileged or not to be disclosed to the Commission approved Acquirer.

However, it is understood that to the extent that Respondents fail to so identify such privileged or not to be disclosed information to the Interim Monitor (a "Failure to Identify"), the Interim Monitor shall not have liability for disclosure of same to the Commission approved Acquirer, unless, notwithstanding a Failure to Identify by Respondents, the Interim Monitor knew or should have known that information was privileged or not to be disclosed, and nonetheless discloses such information to the Commission approved Acquirer.

9. The Interim Monitor shall maintain a record and inform the Commission of all persons (other than representatives of the Commission) to whom confidential information related to this Agreement has been disclosed.
10. Upon termination of the Interim Monitor's duties under this Monitor Agreement, the Interim Monitor shall promptly return to Respondents all material provided to the Interim Monitor by Respondents that is confidential to Respondents and shall destroy any material prepared by the Interim Monitor that contains or reflects any confidential information of Respondents provided that the Interim Monitor provides notice to the Commission staff and the Commission staff does not require the Interim Monitor to maintain the materials; provided, however, notwithstanding the foregoing, the Interim Monitor shall be entitled to retain for its records, on a confidential basis, any materials or documents developed by it in furtherance of its responsibilities and obligations under this Monitor Agreement, regardless of whether such materials contain confidential information. Nothing herein shall abrogate the Interim Monitor's duty of confidentiality, including the obligation to keep such information confidential for a period of five (5) years after the termination of this Monitor Agreement.
11. In addition and except as otherwise permitted in Section 10 above, the Interim Monitor shall keep confidential for a period of five (5) years all other aspects of the performance of its duties under this Monitor Agreement and shall not disclose any confidential or proprietary information relating thereto. To the extent that the

Interim Monitor wishes to retain any employee, agent, consultant or any other third party to assist the Interim Monitor in accordance with the Order, the Interim Monitor shall ensure that such persons execute an appropriate confidentiality agreement.

For the purposes of this Section, information shall not be considered confidential or proprietary to the extent that it is or becomes part of the public domain (other than as the result of any action by the Interim Monitor or by any employee, agent, affiliate or consultant of the Interim Monitor), or to the extent that the recipient of such information can demonstrate that such information was already or becomes known to the recipient at the time of receipt from a source other than Respondents or any director, officer, employee, agent, consultant or affiliate of Respondents when such source is entitled to make such disclosure to such recipient.

12. Nothing in this Monitor Agreement shall require Respondents to disclose any material or information that is subject to a legally recognized privilege or that Respondents are prohibited from disclosing by reason of law or an agreement with a third party.
13. The Interim Monitor shall not have a fiduciary responsibility to the Respondents, but, as set forth in the Order, shall have fiduciary duties to the Commission.
14. Each party shall be reasonably available to the other to discuss any questions or issues that either party may have concerning compliance with the Order as it relates to Respondents.
15. Respondents will pay the Interim Monitor in accordance with the fee schedule attached hereto as Confidential Appendix A for all time spent in the performance of the Interim Monitor's duties including all monitoring activities related to the efforts of the Commission-approved Acquirer of the Monitored Assets (including any and all such activities performed prior to the date of this Agreement), all work in connection with the negotiation and preparation of this Monitor Agreement, and all reasonable and necessary travel time. Every six months such hourly rates should be reviewed and may be adjusted by agreement with Respondents.
  - a. In addition, Respondents will pay (i) all out-of-pocket expenses incurred by the Interim Monitor in the performance of the Interim Monitor's duties, including any auto, train or air travel in the performance of the Interim Monitor's duties, international telephone calls, and (ii) all fees and disbursements reasonably incurred by such consultants, accountants, attorneys, investment bankers, business brokers, appraisers, and other representatives and assistants as are reasonably necessary to carry out the Interim Monitor's duties.
  - b. Any expense charged to a credit card incurred in a currency other than U.S. dollars shall be converted into dollars for expense

reimbursement purposes at the exchange rate used for said credit card transaction and any ancillary cash expenses for which a credit card is not possible shall be converted at the exchange rate for which said currency was purchased.

- c. The Interim Monitor shall have full and direct responsibility for compliance with all applicable laws, regulations and requirements pertaining to work permits, income and social security taxes, unemployment insurance, worker's compensation, disability insurance, and the like.
16. Respondents hereby confirm their obligation to indemnify the Interim Monitor and hold the Interim Monitor harmless in accordance with and to the extent required by the Orders (and, upon direction by the Commission to the Interim Monitor to divest any Monitored Assets).

Without in any way limiting the generality of the foregoing, Respondents shall indemnify the Interim Monitor and any subcontractor and their respective consultants, agents, partners, principals, directors, officers, members, managers and employees (the "Indemnified Parties") and hold the Indemnified Parties harmless (regardless of form of action, whether in contract, statutory law, tort or otherwise) against any losses, claims, damages, liabilities or expenses arising out of or in connection with, the performance of the Interim Monitor's duties and obligations including all reasonable fees of counsel and other reasonable expenses incurred in connection with the preparations for, or defense of, any claim, whether or not resulting in any liability, except to the extent that such losses, claims, damages, liabilities, or expenses are finally judicially determined to result from the willful misconduct of the Interim Monitor. This section shall survive the termination or expiration of this Agreement.

17. The Interim Monitor's maximum liability to the Respondents relating to services rendered pursuant to this Agreement (regardless of the form of the action, whether in contract, statutory law, tort, or otherwise) shall be limited to the total sum of the fees paid to the Interim Monitor by Respondents, not to exceed two hundred fifty thousand dollars (\$250,000). **IN NO CIRCUMSTANCES WHATSOEVER SHALL INTERIM MONITOR BE LIABLE FOR ANY SPECIAL, INCIDENTAL, CONSEQUENTIAL OR PUNITIVE DAMAGES.** The Interim Monitor is not responsible for evaluating the legal or technical sufficiency of any documents, materials or actions of Respondents or the Commission-approved Acquirer under the Order. The Interim Monitor shall not incur any liability of any nature for the failure of Respondents, any Commission-approved Acquirer, or the Commission to perform any acts, or not perform any acts. This section shall survive the termination or expiration of this Agreement.
18. Respondents agree that the Respondents' obligations to indemnify the Interim Monitor and the Indemnified Parties extend to any agreement that is entered between the Interim Monitor and any Commission-approved Acquirer and that



relates to the Interim Monitor's responsibilities under the Monitor Agreement or the Order. This section shall survive the termination or expiration of this Agreement.

19. Upon this Monitor Agreement becoming effective, the Interim Monitor shall be permitted, and Respondents shall be required, to notify the Commission-approved Acquirer with respect to this appointment as Interim Monitor.
20. In the event that a disagreement or dispute between Respondents and the Interim Monitor cannot be resolved by the parties, either party may seek the assistance of the individual in charge of the Commission's Compliance Division to resolve this issue. In the event that such disagreement or dispute cannot be resolved by the parties, the parties shall submit the matter to binding arbitration before the American Arbitration Association under its Commercial Arbitration Rules, but only if the individual in charge of the Commission's Compliance Division determines within the Commission's reasonable discretion that such a matter is appropriate for submission to the American Arbitration Association. Binding arbitration shall not be available, however, to resolve any disagreement or dispute concerning the Respondents' obligations pursuant to the Order.
21. This agreement shall be subject to the substantive law of the State of New Jersey (regardless of any other jurisdictions choice of law principles).
22. This Monitor Agreement shall terminate when the last obligation under the relevant Remedial Agreement(s) has been fully performed, or the Commission has either declined to approve this agreement or appointed a substitute monitor pursuant to the Order, *provided however*, that the Commission may extend this Monitor Agreement as may be necessary or appropriate to accomplish the purposes of the Order. The confidentiality and indemnity obligations of this Monitor Agreement shall survive its termination.
23. In the event that, during the term of this Monitor Agreement, the Interim Monitor becomes aware that it has or may have a conflict of interest that may affect or could have the appearance of affecting the performance by the Interim Monitor of any of its duties under this Monitor Agreement, the Interim Monitor shall promptly inform both Respondents and the Commission of such conflict or potential conflict.
24. In the performance of its functions and duties under this Monitor Agreement, the Interim Monitor shall exercise the standard of care and diligence that would be expected of a reasonable person in the conduct of its own business affairs.
25. This Agreement is for the sole benefit of the Parties hereto and their permitted assigns and the Commission, and nothing herein express or implied shall give or be construed to give any other person any legal or equitable rights hereunder.
26. Any notices or other communication required to be given hereunder shall be deemed to have been properly given if sent by mail or fax (with

acknowledgement of receipt of such fax having been received), to the applicable party at its address below (or to such other address as to which such party shall hereafter notify the other party):

If to the Interim Monitor, to:

Address: William Rahe  
5 N Regent Street  
Suite 502  
Livingston, New Jersey 07039

Telephone Number: 973-992-0505  
Cell Phone: 317-331-3890  
Facsimile: 973-535-1734  
Email: [wrahe@quanticgroup.com](mailto:wrahe@quanticgroup.com) and [toswald@quanticgroup.com](mailto:toswald@quanticgroup.com)

If to Respondents, to:

Address: Sheldon V. Hirt  
Vice President, Associate Counsel and Assistant Corporate  
Secretary  
Barr Laboratories, Inc.  
400 Chestnut Ridge Road  
Woodcliff Lake, NJ 07677-7668

Telephone Number: 201-930-3381  
Facsimile: 888-843-0563  
Email: [SHirt@barrlabs.com](mailto:SHirt@barrlabs.com)

If to the Commission, to:

Address: Federal Trade Commission  
Attn: David Von Nirschl  
601 New Jersey Avenue, N.W.  
Washington, DC 20580


Telephone: 202-326-3213  
Email: [DNirschl@ftc.gov](mailto:DNirschl@ftc.gov)

27. This Monitor Agreement shall become binding upon execution, although it will be subject to approval by the Commission.

IN WITNESS WHEREOF, the parties hereto have executed this Monitor Agreement as of the date first above written.

**BARR PHARMACEUTICALS, INC.**

**INTERIM MONITOR**

  
By: Frederick J. Killian  
Its: Vice President, General Counsel and  
Secretary

  
F. William Rahe