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| **IN RE YAZ®, YASMIN®, OCELLA® LITIGATION** | **SUPERIOR COURT OF NEW JERSEY LAW DIVISION: BERGEN COUNTY** |
| | **CASE NO. 287** |
| ***This Document Relates to All Actions*** | **CIVIL ACTION** |

FILED
OCT 12 2010
BRIAN R. MARTINOTTI
J.S.C.

**CASE MANAGEMENT ORDER NO. 16**
**AMENDMENTS TO CASE MANAGEMENT ORDER NO. 8**

**(Defendant's Fact Sheet and the Production of Third-Party Data Relating to Plaintiffs' Dispensing/Prescribing Health Care Provider Prescribing Practices)**

The parties having agreed to amend Case Management Order No. 8 ("CMO No. 8") dated July 22, 2010, CMO No. 8 is hereby amended as follows:

1. In Section IV and VIII(5) of the Defendant's Fact Sheet ("DFS"), Defendants have agreed, without objection, to answer certain questions and provide certain data relating to the dispensing and prescribing practices of Plaintiffs' Dispensing/Prescribing Health Care Providers as it relates to Yaz, Yasmin, and Ocella if such data is within their possession, custody or control.

2. One or more of the Bayer defendants license information and data responsive to Section IV and VIII(5) of the DFS from Source Healthcare Analytics, Inc. ("SHA"). SHA has authorized Bayer to provide a copy of the responsive data to the Plaintiffs, with no fee, upon execution of the *Third-Party Data Use Agreement* attached hereto as Exhibit "1" by the individual Plaintiff's counsel to whom the data will be produced.

3. Bayer shall, upon receipt of an executed *Third-Party Data Use Agreement* from Plaintiff's counsel (sent to Bayer's counsel by E-mail to aroy@eckertseamans.com with a cc: copy of the E-mail to SHA's representatives at Corey.Babington@source.wolterskluwer.com and Kent.Matsumoto@source.wolterskluwer.com):

a) supplement its response to Section IV and VIII(5) of any DFS already provided to Plaintiff and produce all responsive documents within fifteen (15) days of receiving the executed the *Third-Party Data Use Agreement*;

b) produce all responsive data and documents pursuant to Section IV and VIII(5) of the DFS pursuant to CMO No. 8 in cases where a DFS has not yet been provided to Plaintiff.

4. All provisions of CMO No. 8 other than those amended herein shall remain unchanged and in full force and effect.

**IT IS SO ORDERED.**

Hon. Brian R. Martinotti, J.S.C.

FP01/ 6384343.1

# EXHIBIT 1

# THIRD PARTY DATA USE AGREEMENT (LITIGATION)

This **THIRD PARTY DATA USE AGREEMENT (LITIGATION)** ("**Agreement**") is by and among Source Healthcare Analytics, Inc., a Delaware corporation with its principal place of business at 2394 East Camelback Road, Phoenix, Arizona 85016 ("**SHA**"), Bayer HealthCare Pharmaceuticals Inc., with its principal place of business at 6 West Belt Road, Wayne, New Jersey, 07470 ("**Bayer**") and ***PLAINTIFF'S LAW FIRM***_____, with its principal place of business at _____ ("**Data User**"), and SHA, Bayer, and Data User may be individually referred to herein as a "**party**" or may be collectively referred to herein as the "**parties.**"

THE PARTIES AGREE TO THE FOLLOWING:

1. **Effective Date.** This Agreement shall only become effective as of the earlier of: (i) the date last signed by all parties, or (ii) the date that Data User receives access to the SHA Data ("**Effective Date**").

2. **Scope of this Agreement.** Data User is currently involved in litigation with Bayer (the "**Litigation**") titled:

   - *In re: Yaz, Yasmin, Ocella Litigation*, Court of Common Pleas, Philadelphia County, September Term, 2009;
   - *In re: Yaz, Yasmin, and Ocella Contraceptive Cases*, California Judicial Council Coordination Proceeding No. 4608, Los Angeles Superior Court.
   - *In re: Yasmin and Yaz (Drospirenone) Marketing and Sales Practices and Products Liability Litigation*, MDL 2100 (S.D. Ill.);
   - *In re: Yaz, Yasmin, Ocella Litigation*, Superior Court of New Jersey, Law Division, Bergen County, Case No. 187

   As part of discovery in the Litigation, Data User seeks to receive, use and/or disclose (subject to a Court-approved protective order) all or part of the following data product(s)/service(s) that Bayer previously licensed from SHA ("**SHA Data**" or "**Data**"):

   **SHA Data** includes information or data licensed by Bayer (including the Bayer Affiliates listed below) from SHA regarding prescriptions written by individual physicians or other healthcare providers for: (1) oral contraceptives, including but not limited to Yaz, Yasmin and Ocella; (2) other combined contraceptives, including patches, rings or other methods of delivery; (3) prescription medications to treat acne; or (4) medications for the treatment of PMS and PMDD. For purposes of this definition, prescription information or data shall be deemed to include any information or data regarding the name or type of product prescribed, the number of prescriptions, the number of refills and the dates of prescriptions or refills, to the extent any such information was licensed by Bayer

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(including Bayer Affiliates) from SHA, and any reports analyzing this data provided by SHA to Bayer and Bayer Affiliates.

**SHA Data** also includes any license agreement, or amendment thereto, pursuant to which Bayer (including Bayer Affiliates) licensed information or data from SHA, and any correspondence or communications relating to any such license agreement or amendment thereto.

**SHA Data** further includes any data or information derived from any SHA Data licensed by Bayer. By the signature below of an authorized representative of SHA, this Agreement constitutes SHA's prior written permission to Bayer to disclose such data to Data User, subject to the terms and conditions contained in this Agreement including specifically, receipt of written consents from all Data Agents (as defined in Section 7 below).

As used herein, **Bayer Affiliates** shall include:

Bayer Corporation
Bayer Healthcare, LLC
Bayer Pharmaceuticals Corporation
Bayer Healthcare Pharmaceuticals, Inc.
Berlex Laboratories, Inc.
Berlex, Inc.
Bayer Schering Pharma AG
Bayer AG
Intendis, Inc.

3. **Data Delivery.** Bayer will have sole responsibility for providing Data User with access to the SHA Data. SHA has no obligation to deliver any SHA Data or provide support of any kind to Bayer or Data User unless expressly provided here.

4. **Contact Information.**

Data User: [Name]
[Title]
[Address]
[Telephone]
[E-mail]

Bayer: Timothy Coon
600 Grant St.
Pittsburgh PA 15219
412-566-6000
tcoon@eckertseamans.com

5. **Permitted Scope of Data Use.** The parties agree that the SHA Data may be used solely in accordance with this Agreement and for the purpose(s) and in the manner expressly described below ("Permitted Use(s)"):

SHA Data may be used in connection with discovery, motion practice, trial and appeal in the Litigation pursuant to the terms of the Protective Order (as defined in Section 8(a) below). The Permitted Uses shall terminate at the conclusion of the Litigation identified in Section 2 on the last to occur of the following dates: (1) entry of a final order and judgment disposing of all claims; (2) exhaustion of all appellate rights relating to any final order and judgment; (3) expiration of the time to appeal any final order and judgment; or (4) final settlement of all claims.

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6. **Restrictions on Data User's Use of SHA Data.** The Permitted Use(s) described in the preceding Section 5 are subject to all of the following restrictions:

a. SHA Data may only be used in accordance with this Agreement.

b. SHA Data cannot be used to identify an individual patient or pharmacy or for any other unlawful purpose. SHA Data must be delivered to Data User only in de-identified format in compliance with the Health Insurance Portability and Accountability Act of 1996 and its implementing regulations. Data User represents and warrants that it will not attempt, directly or indirectly, to re-identify any SHA Data to identify an individual or pharmacy. SHA may require Bayer to immediately suspend delivery of any SHA Data to Data User in the event that SHA has a good faith reason to believe that identifiable data will be or is included with or in any SHA Data. Data User shall ensure that the SHA Data will not be used by or on behalf of Data User in any way to exhibit, reference, access or generate any individual, pharmacy or hospital level data. Data User represents and warrants that it will not attempt to link, on an individual basis, any other information to the SHA Data. Data User further represents and warrants that it maintains, and will continue to maintain, appropriate access controls to physically, technically, and administratively separate any SHA Data. Data User agrees to notify SHA immediately if any individual or pharmacy identifiable data is received by Data User. Data User agrees that subject to SHA's direction, they will either: (1) promptly return to SHA any SHA Data that contains identifiable data, or (2) destroy such Data and copies thereof.

c. Except for the Permitted Use(s), Data User may not use any SHA Data for Data User's own benefit or for the benefit of any other person or entity. Further, Data User may resell, sublicense, copy, duplicate or otherwise distribute, disclose or permit access to SHA Data by any third party (including affiliates of Data User).

d. Data User acknowledges that SHA has an obligation to handle medical information in a legally appropriate and confidential manner. In addition to any other remedy or right hereunder, SHA shall have the right to obtain equitable relief in the event that Data User breaches any obligation herein.

7. **Additional Required Written Consents.** The following third-parties have provided Source with written consent for use of third party data consistent with the Permitted Use(s) permitted herein, from the following third-parties whose proprietary data is included within certain SHA Data ("**Data Agents**"):

American Medical Association (AMA)
American Osteopathic Association (AOA)
SDI Health, LLC
American Academy of Physician Assistants (AAPA)

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American College of Nurse Midwives (ACNM)

ACNM's consent to disclosure of its data by Bayer to a Data User is conditioned upon Bayer including the following statement along with any transmission ACNM data to a Data User:

> "In the matter of *In Re Yaz, Yazmin, Ocella Litigation*, pursuant to Case Management Order #5 in the Superior Court of New Jersey, Law Division, Civil Action Case #287, Clause I(B); Case Management Order #3(a) Court of Common Pleas Philadelphia County, September Term 2009, Number 1307, Clause I(C); in the United States District Court, Southern District of Illinois, 3:09-md-02100-DRH-PMF, Clause I(C), and Los Angeles Superior Court, Case Management Order No. 3, California JCCP No. 4608, in response to a request from defendant Bayer Healthcare, the American College of Nurse-Midwives through its licensees Source Healthcare Analytics and Bayer Healthcare, hereby consents to Bayer Healthcare's disclosure to the Parties certain proprietary prescriber-level data pursuant to the understanding that ACNM hereby elects to avail itself, and therefore be bound by, the terms and conditions of the Protective Orders in the aforementioned litigation, thereby becoming a Supplying Party for purposes of those Orders such that the information ACNM is disclosing will be treated as "Confidential Information" subject to the Orders of the Superior Court of New Jersey, the Court of Common Pleas of Philadelphia County, and the U.S. District Court for the Southern District of Illinois."

8. **Confidentiality.**

a. SHA's willingness to enter into this Agreement is expressly conditioned upon Bayer's and Data User's willingness to treat SHA Data as confidential information subject to the terms of a valid, Court-approved protective order. A copy of the applicable Protective Order(s) in the Litigation ("Protective Order(s)") is attached hereto as an exhibit. Bayer and Data User each agree that they will not disclose any SHA Data during the Litigation unless such disclosure fully complies with the terms of the attached Protective Order(s).

b. Data User shall ensure that: (i) any employees or agents who receive any SHA Data is apprised of and appreciates the confidential and proprietary nature of the SHA Data, and (ii) each such employee agrees to the confidentiality obligations herein and refrains from disclosing or discussing the SHA Data with anyone other than the Court or required employees of Data User, Bayer or SHA. Data User's employees shall only receive those portions of the SHA Data necessary to fulfill Data User's requirements in connection with the Litigation and in accordance with the Permitted Use.

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c. Data User agrees not to remove or alter any SHA confidentiality, copyright or proprietary notice appearing on any SHA Data received from Bayer. In addition, any documents or materials prepared by Data User which contain information derived from any SHA Data shall be marked or designated confidential pursuant to the terms and procedures set forth in the Protective Order and without regard to whether such information may or will be disclosed to any other person or party.

d. Except in accordance with the terms of the Protective Order(s) referenced above, no part of the SHA Data shall be published, quoted or reproduced by Data User.

e. No part of the SHA Data shall be published, quoted, made or reproduced by Data User for advertising, promotional or public relations purposes.

f. Data User accepts sole responsibility for ensuring that Data user's employees comply with the terms of this Section of the Agreement and the Protective order(s). Data User agrees that it is directly and separately liable for any breach of such terms by Data Users employees.

9. **Ownership.** Bayer and Data User acknowledge that the Data provided under this Agreement are proprietary and confidential to SHA and that Bayer and Data User have the right only to use such Data in accordance with the terms of this Agreement. Except as otherwise provided for herein, SHA retains all right, title and interest in, to, and under the Data.

10. **Term and Termination.** The term of this Agreement shall begin on the Effective Date and shall end at the (i) the expiration or termination of the Permitted Use(s); or (ii) any earlier termination as permitted under the Agreement. Upon the termination or expiration of this Agreement, Data user shall at SHA's option destroy or return to Bayer or to SHA, all SHA Data, and if applicable, an authorized representative of Data User shall certify in writing to SHA, with a copy to Bayer, that Data user has destroyed or returned to Bayer or SHA all SHA Data.

11. **No Warranty.** ANY SHA DATA PROVIDED TO DATA USER IN CONNECTION WITH THIS AGREEMENT IS PROVIDED TO DATA USER "AS-IS" AND SHA MAKES NO REPRESENTATION OR WARRANTY, EXPRESS OR IMPLIED, TO DATA USER OR TO BAYER IN CONNECTION WITH THE SHA DATA, INCLUDING THE IMPLIED WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE.

12. **Limitation of Liability.** THE PARTIES ACKNOWLEDGE AND AGREE THAT SHA SHALL HAVE NO LIABILITY TO ANY OTHER PARTY UNDER THIS AGREEMENT, INCLUDING BUT NOT LIMITED TO, ANY LIABILITY ARISING FROM THE INACCURACY OR INCOMPLETENESS OF THE DATA. IN NO EVENT SHALL SHA BE LIABLE FOR ANY INCIDENTAL OR CONSEQUENTIAL

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DAMAGES INCLUDING BUT NOT LIMITED TO, LOST BUSINESS, LOST PROFITS OR THIRD PARTY CLAIMS, WHETHER FORESEEABLE OR NOT, EVEN IF SHA HAS BEEN ADVISED OF THE POSSIBILITY OF SUCH DAMAGES. The parties acknowledge and agree that a breach of Data User or its employees of the provisions of this Agreement will cause SHA and/or its affiliates irreparable injury and damage which may not be compensable by money damages, and, therefore, Data User agrees that SHA and/or its affiliates shall be entitled to injunctive or other relief to prevent such a breach and to secure enforcement of the terms of this Agreement, in addition to any other remedies which may be available. Without limiting the availability to SHA of any other rights or remedies, if Data User breaches any of the terms of this Agreement, SHA reserve the right to immediately terminate this Agreement upon notice to Bayer and Data User.

13. **Indemnification.** Bayer and the individual Data User (Plaintiffs' law firm) to whom Bayer produces SHA Data in the Litigation each respectively agree to defend and indemnify SHA and hold SHA harmless for any and all claims, damages, costs, demands, or other liabilities (each a "Claim") arising from or relating to any use of the SHA Data hereunder or a breach of this Agreement by Data User. A Data User shall be responsible for defense and indemnification of SHA under this Section only if a Claim relates to SHA Data provided to that Data User. A Data User is not responsible for defense and indemnification of SHA under this Section if a Claim relates to SHA Data provided to another Data User also involved in the Litigation. SHA shall notify Bayer and Data User of each such Claim after each Claim becomes known to SHA.

14. **Notices.** All notices, demands or other communications required hereunder shall be given or made in writing and shall be delivered personally or sent prepaid (a) by certified or registered first class mail with return receipt requested or (b) by a nationally-recognized common carrier's overnight courier service, addressed to the receiving party at the address first written above or such other address as the receiving party may advise in writing to use hereunder. Further, in the case of SHA, the notice must be sent to the attention of the "President & CEO" with a copy to the "Legal Department."

15. **Miscellaneous.** This Agreement sets forth the entire agreement between the parties and supersedes prior proposals, agreements and representations related to the subject matter of this Agreement, whether written or oral. No modifications, amendments or waiver of any of the provisions of this Agreement shall be binding upon the parties unless made in writing and duly executed by authorized representatives of all parties. No party may assign, transfer or sublicense any portion of this Agreement or the Data provided hereunder without the express prior written consent of SHA. Any attempt to assign, transfer or sublicense by Data User or Bayer shall be void. This Agreement may be executed in one or more counterparts, each of which shall be deemed an original, and all of which together shall constitute one and the same document. The headings of the paragraphs hereof are used for convenience only and shall not affect the meaning or interpretation of the content thereof. This Agreement and the relationship of the parties in connection with the subject matter of this Agreement shall be governed by and

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determined in accordance with the laws of the State of Arizona. The failure to enforce at any time the provisions of this Agreement or to require at any time performance by the other parties of any of the provisions hereof shall in no way be construed to be a waiver of such provisions or to affect either the validity of this Agreement (or any part hereof), or the right of any of the parties thereafter o enforce each and every provision in accordance with the terms of this Agreement. If any provision of this Agreement is held to be invalid or unenforceable by any judgment of a tribunal of competent jurisdiction, the remainder of this Agreement shall not be affected by such judgment, and the Agreement shall be carried out as nearly as possible according to its original terms and intent. However, if the original intent of the parties cannot be preserved, this Agreement shall terminate upon the effective date of such judgment.

**[SIGNATURE PAGE TO FOLLOW]**

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SHA, Bayer and Data User acknowledge their receipt and acceptance of the terms and conditions of this Agreement by the signature below of their respective authorized representatives.

**DATA USER:**

By: _____
Printed Name: _____
Title: _____
Date: _____

**BAYER HEALTHCARE PHARMACEUTICALS INC.:**

By: Timothy S Coon
Printed Name: TIMOTHY S COON
Title: LEGAL COUNSEL FOR BHCP
Date: 9/3/10

**SOURCE HEALTHCARE ANALYTICS, INC.**

By: Michelle Woker
Printed Name: Michelle Woker
Title: Senior Vice President
Date: Operations & Data Strategy

Approved as to Legal Form
CTM
9/8/10
Legal Dept.

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