

## **EXHIBIT P**

### **ZYDUS INJUNCTIVE RELIEF TERM SHEET**

#### **I. DEFINITIONS**

- A. “Authorized Generic” shall mean “authorized generic drug” or the manufacturer of an “authorized generic drug” as that term is defined under 21 CFR § 314.3(b).
- B. “Cancer-Related Pain Care” shall mean care that provides relief from pain resulting from a patient’s active cancer or cancer treatment, as distinguished from treatment provided during remission.
- C. “CDC Guideline Recommendations” shall mean the 12 enumerated Recommendations published by the U.S. Centers for Disease Control and Prevention (CDC) for the prescribing of opioid pain medication for patients 18 and older in primary care settings as part of its 2016 Guideline for Prescribing Opioids for Chronic Pain (CDC Guidelines), as updated or amended by the CDC.
- D. “Downstream Customer Data” shall mean transaction information that Zydus collects relating to its direct customers’ sales to Downstream Customers, including but not limited to chargeback data tied to Zydus providing certain discounts, “867 data,” and IQVIA data. For the avoidance of doubt, Downstream Customer Data is limited to information collected by Zydus in the ordinary course of Zydus business.
- E. “Downstream Customers” shall mean the customers to which Zydus’s direct customers sell Zydus product.
- F. “Effective Date” shall have the same meaning as in Section I of the Zydus Settlement Agreement.
- G. “End-of-Life Care” shall mean care for persons with a terminal illness or at high risk for dying in the near future in hospice care, hospitals, long-term care settings, or at home.
- H. “Excluded Drugs” shall mean (1) medications with a FDA-approved label that lists the treatment of OUD, opioid abuse, addiction and/or dependence among their “indications and usage”; (2) injectable medications administered at or by a Health Care Provider (except when administered at a retail pharmacy); (3) raw materials and/or immediate precursors used in the manufacture or study of Opioids or Opioid Products, but only when such materials and/or immediate precursors are sold or marketed exclusively to DEA-licensed manufacturers or DEA-licensed researchers; (4) medications for reversing opioid overdose; and (5) for the avoidance of doubt, methadone, buprenorphine, buprenorphine-naloxone, and naloxone. Notwithstanding the foregoing, Subutex® and generic formulations thereof are not Excluded Drugs.
- I. “Health Care Provider” shall mean any U.S.-based physician or other health care practitioner who is licensed to provide health care services or to prescribe pharmaceutical

products and any medical facility, practice, hospital, clinic or pharmacy in the United States and its territories.

- J. “In-Kind Support” shall mean payment or assistance in the form of goods, commodities, services, or anything else of value.
- K. “Lobby” and “Lobbying” shall have the same meaning as “lobbying activities” and “lobbying contacts” under the federal lobbying disclosure act, 2 U.S.C. § 1602 *et seq.*, and any analogous state or local provisions governing the person or entity being lobbied in that particular state or locality. As used in this document, “Lobby” and “Lobbying” include Lobbying directly or indirectly, through grantees or Third Parties.
- L. “Opioid(s)” shall mean all naturally occurring, synthetic, or semisynthetic substances that interact with opioid receptors and act like opium. The term “Opioid(s)” shall not include Excluded Drugs.
- M. “Opioid Product(s)” shall mean all current and future medications containing Opioids approved by the U.S. Food & Drug Administration (FDA) and listed by the DEA as Schedule II, III, or IV drugs pursuant to the federal Controlled Substances Act, including but not limited to codeine, fentanyl, hydrocodone, hydromorphone, meperidine, morphine, oxycodone, oxymorphone, tapentadol, and tramadol. The term “Opioid Product(s)” shall not include Excluded Drugs.
- N. “OUD” shall mean opioid use disorder defined in the *Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM–5)*, as updated or amended.
- O. “Promote,” “Promoting,” and “Promotion(al)” shall mean dissemination of information or other practices intended or that could be reasonably anticipated to increase sales, prescriptions, the utilization of prescription products, or that attempt to influence prescribing practices or branded formulary decisions in the United States and its territories.
- P. “Qualified Researcher” shall mean any researcher holding a faculty appointment or research position at an institution of higher education, a research organization, a nonprofit organization, or a government agency.
- Q. “Settling State” has the same definition as in Section I of the Settlement Agreement.
- R. “Suspicious Order” shall have the same meaning as provided by the Controlled Substances Act, 21 U.S.C. §§ 801-904, and the regulations promulgated thereunder and analogous state laws and regulations.
- S. “Third Party” shall mean any person or entity other than Zydus or a government entity.
- T. “Treatment of Pain” shall mean the provision of therapeutic modalities to alleviate or reduce pain except through the administration of non-Opioids and non-Opioid Products.

- U. “Unbranded Information” shall mean any information that does not identify one or more specific products.
- V. “Zydus” shall mean Zydus Pharmaceuticals (USA) Inc. and each of its current subsidiaries, successors, joint ventures, divisions and assigns. It shall also mean officers, directors, independent contractors, consultants, agents, employees, partners, and principals, provided that they are acting within the scope of their engagement or employment.
- W. “Zydus’s Opioid Business” shall mean Zydus’s business operations relating to the manufacture and sale of Opioid Product(s) in the United States and its territories.

## **II. SCOPE AND ENFORCEMENT**

- A. All of the provisions of this Exhibit shall apply to the operation of Zydus’s Opioid Business by Zydus and its respective successors and assigns, including any subsequent purchaser, regardless whether the purchaser buys all or just a portion of Zydus’s Opioid Business. For the avoidance of doubt, nothing in this Exhibit applies to the operation of a subsequent purchaser(s)’ pre-existing opioid business.

### **B. Term**

1. Unless addressed in Section II.B.2 or Section III.J.1, each provision of this Exhibit shall apply for ten (10) years from the Effective Date.
2. The provisions of Section III.A (“Ban on Promotion”), Section III.H (“General Provisions”) and Section III.I (“Compliance with All Laws and Regulations Relating to the Sale Promotion and Distribution of Any Opioid Product”) shall not be subject to any term.

### **C. Notice and Cure**

1. For the purposes of resolving disputes with respect to compliance with this Exhibit, should any State Attorney General have reason to believe that Zydus has violated a provision of this Exhibit subsequent to the Effective Date, then such Attorney General shall notify Zydus in writing of the specific objection, identify with particularity the provisions of this Exhibit that the practice appears to violate, and give Zydus 30 days to respond to the notification (“Response Period”). Nothing shall prevent such State Attorney General from agreeing in writing to provide Zydus with additional time beyond the 30 days to respond to the notice.
2. Within 30 days of receipt of written notice from such State Attorney General, or longer time if agreed to by the State Attorney General, Zydus shall provide a written response to the Settling States containing either a statement explaining why Zydus believes it is in compliance with this Exhibit or a detailed explanation of how the alleged violation occurred and a statement explaining how and when Zydus intends to remedy or has remedied the alleged violation. Zydus may request a reasonable amount of time to cure any violation through such remedial measures (“Cure Period”)

and the State Attorney General shall not unreasonably withhold approval of such request.

3. Such State Attorney General may not take any action concerning the alleged violation of this Exhibit during the Response and Cure Periods. Nothing shall prevent such State Attorney General from agreeing in writing to provide Zydus with additional time beyond the 30 days to respond to the notice. However, such State Attorney General may take any action, including, but not limited to legal action to enforce compliance with the consent judgment specified by Section II.C, without delay if such State Attorney General believes that, because of the specific practice, a threat to the health or safety of the public requires immediate action.
4. Such State Attorney General may bring an action against Zydus to enforce the terms of the consent judgment specified by Section II.C, but only after providing Zydus an opportunity to respond to the notification as described above or within any other period as agreed to by Zydus and such State Attorney General.
5. Nothing in this Exhibit shall be interpreted to limit any State Attorney General's Civil Investigative Demand ("CID") or investigative subpoena authority, to the extent such authority exists under applicable state law.
6. Nothing herein shall be construed to exonerate any failure to comply with any provision of this Exhibit after the Effective Date, or to compromise the authority of any State Attorney General to take action for any failure to comply with this Exhibit.

### **III. INJUNCTIVE RELIEF**

#### **A. Ban on Promotion**

1. Zydus shall not engage in the Promotion of Opioids or Opioid Products, including but not limited to:
  - a. Employing or contracting with sales representatives or other persons to Promote Opioids or Opioid Products to Health Care Providers or patients or to persons that influence or determine the branded Opioid Products included in formularies for the purpose of advocating for branded Opioid Product formulary access;
  - b. Using speakers, key opinion leaders, thought leaders, lecturers, and/or speaking events for Promotion of Opioids or Opioid Products;
  - c. Sponsoring, or otherwise providing financial support or In-Kind Support to medical education programs relating to Opioids or Opioid Products;
  - d. Creating, sponsoring, operating, controlling, or otherwise providing financial support or In-Kind Support to any website, network, and/or social or other media account for the Promotion of Opioids or Opioid Products;

- e. Creating, sponsoring, distributing, or otherwise providing financial support or In-Kind Support for materials Promoting Opioids or Opioid Products, including but not limited to brochures, newsletters, pamphlets, journals, books, and guides;
- f. Creating, sponsoring, or otherwise providing financial support or In-Kind Support for advertisements that Promote Opioids or Opioid Products, including but not limited to internet advertisements or similar content, and providing hyperlinks or otherwise directing internet traffic to advertisements; and
- g. Engaging in Internet search engine optimization or other techniques designed to Promote Opioids or Opioid Products by improving rankings or making content appear among the top results in an Internet search or otherwise be more visible or more accessible to the public on the Internet.

2. Notwithstanding Section III.A.1, III.A.5, and III.C, Zydus may:

- a. Maintain a corporate website;
- b. Maintain a website for any Opioid Product that contains principally the following content: the FDA-approved package insert, medication guide, and labeling, and a statement directing patients or caregivers to speak with a licensed Health Care Provider;
- c. Provide information or support the provision of information as expressly required by law or any state or federal government agency with jurisdiction in the state where the information is provided;
- d. Provide the following by mail, electronic mail, on or through Zydus's corporate or product websites, or through other electronic or digital methods: FDA-approved package insert, medication guide, approved labeling for Opioid Products or other prescribing information for Opioid Products that are published by a state or federal government agency with jurisdiction in the state where the information is provided;
- e. Provide scientific and/or medical information in response to an unsolicited request by a Health Care Provider consistent with the standards set forth in the FDA's Draft Guidance for Industry, *Responding to Unsolicited Requests for Off-Label Information About Prescription Drugs and Medical Devices* (Dec. 2011, as updated or amended by the FDA) and Guidance for Industry, *Good Reprint Practices for the Distribution of Medical Journal Articles and Medical or Scientific Reference Publications on Unapproved New Uses of Approved Drugs and Approved or Cleared Medical Devices* (Jan. 2009, as updated or amended by the FDA);
- f. Provide a response to any unsolicited question or request from a patient or caregiver, directing the patient or caregiver to the FDA-approved labeling

or to speak with a licensed Health Care Provider without describing the safety or effectiveness of Opioids or any Opioid Product or naming any specific provider or healthcare institution; or directing the patient or caregiver to speak with their insurance carrier regarding coverage of an Opioid Product;

- g. Provide Health Care Economic Information, as defined at 21 U.S.C. § 352(a), to a payor, formulary committee, or other similar entity with knowledge and expertise in the area of health care economic analysis consistent with standards set forth in the FDA's Draft Questions and Answers Guidance for Industry and Review Staff, *Drug and Device Manufacturer Communications With Payors, Formulary Committees, and Similar Entities* (Jan. 2018), as updated or amended by the FDA;
  - h. Provide information, through a product catalog or similar means, related to an Opioid or Opioid Product, including, without limitation, pricing information, weight, color, shape, packaging size, type, reference listed drug, National Drug Code label, and such other descriptive information (including information set forth in a standard Healthcare Distribution Alliance Form or technical data sheet and the FDA approval letter) sufficient to identify the products available, to place an order for a product, and to allow the product to be loaded into a customer's inventory and ordering system or a third party pricing compendia;
  - i. Sponsor or provide financial support or In-Kind Support for an accredited or approved continuing medical education program required by either an FDA-approved Risk Evaluation and Mitigation Strategy (REMS) program or other federal or state law or regulation applicable in the state where the program is provided through an independent Third Party, which shall be responsible for the continuing medical education program's content without the participation of Zydus;
  - j. Provide information relating to the pricing and availability of any Opioid Product and negotiate contract and pricing terms with customers;
  - k. Provide Unbranded Information in connection with managing pain in End-of-Life Care and/or Cancer-Related Pain Care relating to: the use of Opioids for managing such pain, as long as the Unbranded Information identifies Zydus as the source of the information; and
  - l. Provide rebates, discounts, and other customary pricing adjustments to DEA-registered customers and contracting intermediaries, such as Buying Groups, Group Purchasing Organizations, and Pharmacy Benefit Managers, except as prohibited by Section III.F.
3. Zydus shall not engage in the following specific Promotional activity relating to any products for the treatment of Opioid-induced side effects (for the avoidance of doubt,

“Opioid-induced side effects” does not include addiction to Opioids or Opioid Products):

- a. Employing or contracting with sales representatives or other persons to Promote products for the treatment of Opioid-induced side effects to Health Care Providers or patients;
  - b. Using speakers, key opinion leaders, thought leaders, lecturers, and/or speaking events for Promotion of products for the treatment of Opioid-induced side effects;
  - c. Sponsoring, or otherwise providing financial support or In-Kind Support to medical education programs relating to products for the treatment of Opioid-induced side effects;
  - d. Creating, sponsoring, or otherwise providing financial support or In-Kind Support for advertisements that Promote products for the treatment of Opioid-induced side effects, including but not limited to internet advertisements or similar content, and providing hyperlinks or otherwise directing internet traffic to advertisements; and
  - e. Engaging in any other Promotion of products for the treatment of Opioid-induced side effects in a manner that encourages the utilization of Opioids or Opioid Products or normalizes the use of Opioids or Opioid Products for chronic pain.
4. Notwithstanding Section III.A.3 directly above, Zydus may engage in Promotional activity for products that may be used for the treatment of Opioid-induced side effects but also have non-Opioid related indications, so long as such Promotion does not explicitly or implicitly associate the product with Opioids or Opioid Products, except for linking to the FDA label associated with that product.

5. Treatment of Pain

- a. Zydus shall not, either through Zydus or through Third Parties, engage in Promotion of the Treatment of Pain in a manner that directly or indirectly encourages the utilization of Opioids or Opioid Products.
- b. Zydus shall not, either through Zydus or through Third Parties, Promote the concept that pain is undertreated in a manner that directly or indirectly encourages the utilization of Opioids or Opioid Products.
- c. Zydus shall not disseminate Unbranded Information, including Unbranded Information about a medical condition or disease state, that contains links to branded information about Opioid Products or generates leads for sales of Opioid Products.

6. For the avoidance of doubt, it shall not be a violation of this Section III.A if Opioids or Opioid Products are referenced within the FDA-approved labels of Zydus's non-Opioid Products.
7. To the extent that Zydus engages in conduct permitted by Sections III.A.2 and III.A.4 above, Zydus shall do so in a manner that is:
  - a. Consistent with the CDC Guideline Recommendations, as applicable; and
  - b. Truthful, non-misleading, accurate, non-deceptive, and does not omit any relevant information.

**B. No Financial Reward or Discipline Based on Volume of Opioid Sales**

1. Zydus shall not provide financial incentives to its sales and marketing employees or discipline its sales and marketing employees based upon sales volume or sales quotas for Opioid Products. However, this provision shall not prohibit financial incentives based on overall company performance. Nor shall it prohibit financial incentives based on sales volume or sales quotas of non-Opioid Products.
2. Zydus shall not offer or pay any remuneration (including any kickback, bribe, or rebate) directly or indirectly, to or from any person in return for the prescribing or use of an Opioid Product. For the avoidance of doubt, this shall not prohibit the provision of rebates and/or chargebacks to the extent permitted by Section III.A.2.1.
3. Zydus's compensation policies and procedures shall be designed to reasonably ensure compliance with this Exhibit.

**C. Ban on Funding/Grants to Third Parties**

1. Zydus shall not directly or indirectly provide financial support or In-Kind Support to any Third Party that Promotes or is for education about Opioids, Opioid Products, the Treatment of Pain, or products intended to treat Opioid-related side effects, including educational programs or websites that Promote Opioids, Opioids Products, or products intended to treat Opioid-related side effects (for the avoidance of doubt, in this Section III.C, "Opioid-related side effects" does not include addiction to Opioids or Opioid Products), but excluding financial support otherwise allowed by this Exhibit or required by a federal or state agency.
2. Zydus shall not create, sponsor, provide financial support or In-Kind Support to, operate, or control any medical society or patient advocacy group relating to any Opioids, Opioid Products, the Treatment of Pain, or products intended to treat Opioid-related side effects.
3. Zydus shall not provide links to any Third-Party website or materials or otherwise distribute materials created by a Third Party relating to any Opioids, Opioid Products, the Treatment of Pain, or products intended to treat Opioid-related side effects.



4. Zydus shall not use, assist, or employ any Third Party to engage in any activity that Zydus itself would be prohibited from engaging in pursuant to this Exhibit.
5. Zydus shall not enter into any contract or agreement with any person or entity or otherwise attempt to influence any person or entity in such a manner that has the purpose or foreseeable effect of limiting the dissemination of information regarding the risks and side effects of using Opioids.
6. Zydus shall not compensate or support Health Care Providers, other than Zydus employees, or organizations to advocate for branded Opioid Product formulary access or treatment guideline changes that would have the effect of increasing access to any Opioid Product by third-party payers, *i.e.*, any entity, other than an individual, that pays or reimburses for the dispensing of prescription medicines, including but not limited to managed care organizations and pharmacy benefit managers. Nothing in this provision affects the limitations on Zydus employees set forth in Section III.A. Notwithstanding anything to the contrary in this Exhibit, this provision does not prohibit the payment of customary rebates or other pricing concessions to third party payors, including state Medicaid programs, as part of an overall pricing agreement, except as prohibited by Section III.F.
7. No director, officer, or management-level employee of Zydus may concurrently serve as a director, board member, employee, agent, or officer of any entity that primarily engages in Promotion relating to Opioids, Opioid Products, the Treatment of Pain, or products intended to treat Opioid-related side effects. Nothing in this provision shall preclude a director, officer, or management-level employee of Zydus from concurrently serving on the board of a hospital, clinic, pharmacy, healthcare system, insurance company, or healthcare benefits administrator.
8. Zydus shall play no role in appointing persons to the board, or hiring persons to the staff, of any entity that primarily engages in Promotion relating to any Opioids, Opioid Products, the Treatment of Pain, or products intended to treat Opioid-related side effects.
9. Nothing herein prohibits or otherwise limits Zydus's right to become a member of any broad based trade association, including, without limitation, the Association for Accessible Medicines (the "AAM").
10. Zydus will be in compliance with Sections III.C.2 and III.C.3 with respect to support of an individual Third Party to the extent that the Settling States determine that such support does not increase the risk of the inappropriate use of Opioids and that Zydus has not acted for the purpose of increasing the use of Opioids.
11. For the avoidance of doubt, nothing in this Section III.C. shall be construed or used to prohibit Zydus from providing financial, In-Kind Support, or providing website links to:
  - a. Universities, medical institutions, or hospitals, for the purpose of addressing, or providing education on (I) the treatment of OUD; (II) the

prevention and treatment of opioid abuse, addiction, or overdose, including medication-assisted treatment for opioid addiction; and/or (III) medications for reversing opioid overdose;

- b. The American Medical Association (AMA), the American Cancer Society (ACS) or any other medical society dedicated to cancer treatment; and
- c. Broad based (*i.e.*, not specific to pain) patient advocacy groups, provided that such support does not increase the risk of the inappropriate use of Opioids.

#### **D. Lobbying Restrictions**

1. Zydus shall not Lobby for the enactment of any provision of any federal, state, or local legislation or promulgation of any provision of any rule or regulation that:
  - a. Encourages or requires Health Care Providers to prescribe Opioid Products or sanctions Health Care Providers for failing to prescribe Opioids or failing to treat pain with Opioids;
  - b. Would have the effect of limiting access to any non-Opioid alternative pain treatments; or
  - c. Pertains to the classification of any Opioid or Opioid Product as a scheduled drug under the Controlled Substances Act.
2. Zydus shall not Lobby against the enactment of any provision of any federal, state or local legislation or promulgation of any provision of any rule or regulation that supports:
  - a. The use of non-pharmacologic therapy and/or non-Opioid pharmacologic therapy to treat chronic pain over or instead of Opioid use, including but not limited to third party payment or reimbursement for such therapies;
  - b. The use and/or prescription of immediate release Opioids instead of extended release Opioids when Opioid use is initiated, including but not limited to third party reimbursement or payment for such prescriptions;
  - c. The prescribing of the lowest effective dose of an Opioid, including but not limited to third party reimbursement or payment for such prescription;
  - d. The limitation of initial prescriptions of Opioids to treat acute pain;
  - e. The prescribing and other means of distribution of naloxone to minimize the risk of overdose, including but not limited to third party reimbursement or payment for naloxone;

- f. The use of urine testing before starting Opioid use and annual urine testing when Opioids are prescribed, including but not limited to third party reimbursement or payment for such testing;
  - g. Evidence-based treatment (such as using medication-assisted treatment with buprenorphine or methadone in combination with behavioral therapies) for OUD, including but not limited to third party reimbursement or payment for such treatment; or
  - h. The implementation or use of Opioid drug disposal systems.
- 3. Zydus shall not Lobby against the enactment of any provision of any federal, state or local legislation or promulgation of any provision of any rule or regulation creating or expanding the operation or use of Prescription Drug Monitoring Programs (PDMPs), including but not limited to provisions requiring Health Care Providers to review PDMPs when Opioid use is initiated and with every prescription thereafter. For the avoidance of doubt, Zydus may Lobby in support of a particular PDMP proposal.
- 4. Notwithstanding the foregoing restrictions in Sections III.D.1–3, III.A, and III.C, the following conduct is not restricted:
  - a. Challenging the enforcement of, or suing for, declaratory or injunctive relief with respect to legislation, rules or regulations referred to in Section III.D.1;
  - b. Communications made by Zydus in response to a statute, rule, regulation, or order requiring such communication;
  - c. Communications by a Zydus representative appearing before a federal or state legislative or administrative body, committee, or subcommittee as a result of a mandatory order or subpoena commanding that person to testify;
  - d. Responding, in a manner consistent with this Exhibit, to an unsolicited request for the input on the passage of legislation or the promulgation of any rule or regulation when such request is submitted in writing specifically to Zydus from a government entity directly involved in the passage of that legislation or promulgation of that rule or regulation;
  - e. Communicating with a federal or state agency in response to a Federal Register or similar notice or an unsolicited federal or state legislative committee request for public comment on proposed legislation;
  - f. Responding to requests from the DEA, the FDA, or any other Federal or state agency and/or participating in FDA or other agency panels at the request of the agency; and

- g. Participate in meetings and other proceedings before the FDA, FDA advisory committee or other FDA committee in connection with the approval, modification of approval, or oversight of its own products.
5. Zydus shall require all of its officers, employees, and agents engaged in Lobbying to certify in writing or by appropriate electronic means to Zydus that they are aware of and will fully comply with the provisions of this Exhibit with respect to Lobbying on behalf of Zydus.

#### **E. Ban on Certain High Dose Opioids**

1. After any related commercial commitments existing as of April 4, 2025 have expired, Zydus shall not manufacture, promote, or distribute any oxycodone pill that exceeds 40 milligrams.

#### **F. Ban on Prescription Savings Programs**

1. Zydus shall not directly or indirectly offer any discounts, coupons, rebates, or other methods which have the effect of reducing or eliminating a patient's co-payments or the cost of prescriptions (*e.g.*, free trial prescriptions) for any Opioid Product.
2. Zydus shall not directly or indirectly provide financial support to any Third Party that offers coupons, discounts, rebates or other methods which have the effect of reducing or eliminating a patient's co-payments or the cost of prescriptions (*e.g.*, free trial prescriptions) for any Opioid Product.
3. Zydus shall not directly or indirectly assist patients, Health Care Providers, or pharmacies regarding the claims and/or prior authorization process required for third-party payers to approve claims involving any Opioid Product.
4. This Section III.F shall not apply if Zydus as an Authorized Generic is required to compete with a legitimate discount initiated by a brand company.

#### **G. Monitoring and Reporting of Direct and Downstream Customers**

1. Zydus shall operate an effective monitoring and reporting system in compliance for its Opioid Products with 21 C.F.R. § 1301.71(a), 21 C.F.R. §1301.74(b), 21 U.S.C. §§ 823, 832, including the following items:
  - a. Incorporate the following into such monitoring and reporting system: (i) utilizing all reasonably available transaction information to identify a Suspicious Order of an Opioid Product by a direct customer; (ii) reasonably available Downstream Customer Data to assist in identifying whether a Downstream Customer poses a material risk of diversion of an Opioid Product; (iii) information Zydus knows or should reasonably know that demonstrates a direct customer's potential for diversion activity, including reports by Zydus's employees, customers, Health Care Providers, law enforcement, state, tribal, or federal agencies, or the media;

and (iv) information Zydus knows or should reasonably know that demonstrates a Downstream Customer's potential for diversion activity, including reports by Zydus's employees, customers, Health Care Providers, law enforcement, state, tribal, or federal agencies, or the media. For the avoidance of doubt, this provision does not require Zydus to collect or purchase any information or data that it does not collect or purchase in the ordinary course of Zydus's business.

- b. Upon request (unless otherwise required by law), Zydus must report to any requesting State Attorney General or State controlled substances regulatory agency any direct customer or Downstream Customer identified by Zydus as posing a material risk of diversion or any customer relationship in such State terminated by Zydus relating to diversion or potential for diversion. These reports shall include the following information, to the extent known to Zydus:
  - i. The identity of the Downstream Customer and the direct customer(s) identified by Zydus engaged in the controlled substance transaction(s), to include each registrant's name, address, business type, and DEA registration number;
  - ii. The dates of reported distribution of controlled substances by direct customers to the Downstream Customer during the relevant time period;
  - iii. The drug name, drug family or NDC and dosage amounts reportedly distributed;
  - iv. The transaction or order number of the reported distribution; and
  - v. A brief narrative providing a description of the circumstances leading to Zydus's conclusion that there is a risk of diversion.
- 2. Zydus shall not provide to any direct customer an Opioid Product to fill an order identified as a potential Suspicious Order unless Zydus's DEA Compliance Department investigates and finds that the order is not suspicious. Where Zydus has investigated a potentially Suspicious Order and determined that the order is not a Suspicious Order, Zydus must document the bases for its determination, and provide such documentation to any State Attorney General or State controlled substances regulatory agency, upon request.
- 3. Upon request, Zydus shall provide full cooperation and assistance to any federal, state or local law enforcement investigations of a Third Party relating to potential diversion or suspicious circumstances involving Opioid Products, including criminal law enforcement agencies, drug control agencies, professional licensing boards, and Attorney General's offices.

4. Zydus agrees that it will refrain from providing an Opioid Product directly to a retail pharmacy location or Health Care Provider. Nothing in this provision, however, prevents Zydus from providing an Opioid Product directly to a mail order pharmacy, distribution center of a third-party (*i.e.*, not related to Zydus) wholesale pharmaceutical distributor, distribution center serving a chain pharmacy, or pharmacy provider that exclusively serves long-term care or hospice providers and their patients. This Section III.G.4 does not apply to Subutex® or generic formulations thereof.

## **H. General Terms**

1. To the extent that any provision in this Exhibit conflicts with federal or state law or regulation, the requirements of the law or regulation will prevail. To the extent that any provision in the Agreement is in conflict with federal or relevant state law such that Zydus cannot comply with both the statute or regulation and a provision of this Exhibit, Zydus may comply with such statute or regulation. Zydus will provide advance written notice to the affected State Attorney(s) General of the statute or regulation that Zydus intends to comply with under this paragraph, and the provision of this Exhibit that is in conflict with the statute or regulation. In the event any State Attorney General disagrees with Zydus's interpretation of the conflict, such State Attorney General reserves the right to pursue any remedy or sanction that may be available regarding compliance with this Exhibit.
2. Zydus shall not make any written or oral statement about Opioids or any Opioid Product that is unfair, false, misleading, deceptive, or unconscionable. For purposes of this paragraph, "Opioid Product" shall also include medications with a FDA-approved label that lists only the treatment of opioid abuse, addiction, and/or overdose as their "indications and usage."
3. Zydus shall not represent that Opioids or any Opioid Product(s) have approvals, characteristics, uses, benefits, or qualities that they do not have. For purposes of this paragraph, "Opioid Product" shall also include medications with a FDA-approved label that lists only the treatment of opioid abuse, addiction and/or dependence as their "indications and usage."
4. For the avoidance of doubt, nothing in this Exhibit is intended to or shall be construed to prohibit Zydus in any way whatsoever from (a) taking legal or factual positions with regard to its Opioid Product(s) in defense of litigation or other legal proceedings or investigations; (b) communicating its positions and responding to media inquiries concerning litigation, investigations, reports, or other documents or proceedings relating to Zydus or its Opioid Products, or (c) maintaining a website explaining its litigation positions and responding to allegations concerning its Opioid Products.
5. Upon the request of any State Attorney General, Zydus shall provide the requesting State Attorney General with copies of the following documents, if received by Zydus after the Effective Date of this Agreement, within 30 days of the request:

- a. Any litigation or civil or criminal law enforcement subpoenas or Civil Investigative Demands relating to Zydus's Opioid Product(s); and
  - b. Warning or untitled letters issued by the FDA regarding Zydus's Opioid Product(s) and all correspondence between Zydus and the FDA related to such letters.
- 6. Notwithstanding the foregoing, the disclosure obligations in III.H.5. shall not apply if the above-referenced subpoenas, Civil Investigative Demands, warning letters, untitled letters, and/or related correspondence are required to be maintained as confidential pursuant to state or federal law.
- 7. Nothing contained herein shall prohibit Zydus from divesting any Opioid or Opioid Product, in each case, including providing technical development services, transferring know-how and patents, and/or providing such other support services in connection therewith, provided that all provisions of this Exhibit shall apply to any subsequent purchase with respect to the divested Opioid or Opioid Product.
- 8. This Exhibit is limited to Zydus's Opioid Business within the United States and its territories or involving Health Care Providers.

**I. Compliance with All Laws and Regulations Relating to the Sale, Promotion, and Distribution of Any Opioid Product**

- 1. Zydus shall comply with all applicable state laws and regulations that relate to the sale, promotion, distribution, and disposal of any Opioids or Opioid Products, provided that nothing in this paragraph requires Zydus to violate federal law or regulations, including but not limited to:
  - a. State controlled substances acts, including all guidance issued by applicable state regulator(s);
  - b. State consumer protection laws; and
  - c. State laws, regulations, and guidelines related to opioid prescribing, distribution, and disposal.

**J. Compliance Deadlines**

- 1. As of the Effective Date, Zydus must be in full compliance with the provisions included in this Exhibit. Notwithstanding the foregoing, Zydus need not have fully incorporated the following into its monitoring and reporting system as of the Effective Date: (i) utilizing all reasonably available transaction information to identify a Suspicious Order of an Opioid Product by a direct customer; (ii) reasonably available Downstream Customer Data; (iii) information Zydus knows or should reasonably know that demonstrates a direct customer's potential for diversion activity, including reports by Zydus's employees, customers, Health Care Providers, law enforcement, state, tribal, or federal agencies, or the media; and (iv) information

Zydus knows or should reasonably know that demonstrates a Downstream Customer's potential for diversion activity, including reports by Zydus's employees, customers, Health Care Providers, law enforcement, state, tribal, or federal agencies, or the media. Specifically, Zydus's compliance with Section III.G.1.a shall be met no later than the 180<sup>th</sup> day following the Effective Date. Nothing shall prevent the Settling States from agreeing in writing to provide Zydus with additional time beyond the 180 days to come into compliance with Section III.G.1.a.

#### **K. Training**

1. Zydus shall provide regular training, at least once per year, to relevant employees on their obligations imposed by this Exhibit.

#### **L. Excluded Drugs**

1. Zydus shall not make any written or oral statement about Excluded Drugs that is unfair, false, misleading or deceptive, or unconscionable, nor shall it represent that Excluded Drugs have approvals, characteristics, uses, benefits, or qualities that they do not have or are inconsistent with the products' FDA-approved labeling.
2. With regard to Excluded Drugs, Zydus shall not employ or contract with sales representatives to request Health Care Providers to write prescriptions for specific Excluded Drugs. For the avoidance of doubt:
  - a. Section III.L.2 does not prohibit Zydus employees from providing Health Care Providers (directly or indirectly) with informational, educational, and instructional resources regarding such Excluded Drugs, including but not limited to product catalogs, product order forms, sample DEA Form 222s, Controlled Substance Ordering System ("CSOS") instructions, Zydus-specific ordering instructions, authorized signers forms, customer complaint forms, patient guides, and use instructions.
  - b. Section III.L.2 does not apply to Excluded Drugs that are for reversing overdose, including but not limited to naloxone.
3. Zydus shall comply with Sections III.G.3 and III.I as if Excluded Drugs were defined as Opioid Products.