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UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF IDAHO

REBECCA GOMPERTS, a licensed physician, and AID ACCESS, GmbH, a corporation, Plaintiffs, vs. ALEX M. AZAR, II, in his official capacity as Secretary, United States Department of Health and Human Services, and his employees, agents and successors in office; UNITED STATES FOOD AND DRUG ADMINISTRATION, a governmental agency; NORMAN SHARPLESS, in his official capacity as the Acting Commissioner of Food and Drugs, and his employees, agents and successors in office; JANET WOODCOCK, M.D., in her official capacity as the Director – Center for Drug Evaluation and Research, and her employees, agents and successors in office; THOMAS CHRISTL, in his official capacity as the Former Director, Office of Drug Security, Integrity, and Response, Center for Drug Evaluation and Research and his employees, agents and successors in office; and ILISA BERNSTEIN, in her official capacity as the current Acting Director, Office of Drug	Case No.: **VERIFIED COMPLAINT**

Security, Integrity, and Response, Center for Drug Evaluation and Research and her employees, agents and successors in office,

Defendants.

Plaintiffs, by and through their undersigned attorney, RICHARD A. HEARN, HEARN LAW, PLC, bring this Complaint on behalf of themselves and women seeking to induce a medical abortion during the early stages of their pregnancies residing in all 50 states, including Idaho, and the District of Columbia against the above-named Defendants, their employees, agents, and successors in office and in support thereof allege the following:

PRELIMINARY STATEMENT

1. For many women seeking to terminate their unwanted pregnancies prior to viability, the only *practical* option is found on the internet.
2. Plaintiffs Dr. Rebecca Gomperts and Aid Access help such women in the U.S. exercise their constitutionally protected right to safely terminate their pregnancies prior to viability.
3. Defendants are actively using the power of the U.S. government to deny Plaintiffs' patients their constitutionally protected right to terminate their unwanted pregnancies prior to viability.

JURISDICTION AND VENUE

4. This Court has subject matter jurisdiction over Plaintiffs' federal claims under Article III of the Constitution and 28 U.S.C. § 1331, as a civil action arising under the laws of the United States; 28 U.S.C. 1346(a)(2), as a civil action against the federal government; 28 U.S.C. § 1343(a)(4), as a civil action to secure equitable or other relief under any Act of

Congress providing for the protection of civil rights; and 5 U.S.C. § 702, as a civil action seeking judicial review of a final agency action.

5. Plaintiffs' action for declaratory and injunctive relief is authorized by 28 U.S.C. §§ 2201, 2202 and 1361, Federal Rules of Civil Procedure 57 and 65, and by the inherent equitable powers of this Court.

6. There exists an actual and justiciable controversy between Plaintiffs and Defendants requiring resolution by this Court and Plaintiffs have no adequate remedy at law.

7. This Court has authority to award costs and attorneys' fees under 28 U.S.C. § 2412.

8. Venue is proper in the District of Idaho pursuant to 28 U.S.C. §§ 1391(b) and (e)(1), and 1402(a)(1), because this is a civil action in which Defendants are an agency, or officers of an agency, of the United States, because a substantial part of the events or omissions giving rise to this action occurred in the District, and because many of Dr. Gomperts' patients -- all of whom are women seeking to induce medical abortions of their pregnancies prior to viability -- are residents of the State of Idaho.

PARTIES

A. Plaintiffs

9. Plaintiff Rebecca Gomperts ("*Dr. Gomperts*") is a licensed physician practicing medicine in Europe. She currently resides in Wien, Austria and Amsterdam, the Netherlands.

10. Dr. Gomperts received her medical training in Amsterdam, the Netherlands.

11. In 2011, Dr. Gomperts completed her Master's in Public Policy at Princeton University and, in 2014, Dr. Gomperts completed her Ph.D. at the Karolinska Institute in Sweden.

12. Dr. Gomperts is licensed to practice medicine in Austria.

13. Dr. Gomperts is the founder and Director of both "Women on Waves" and "Women on Web."

14. Dr. Gomperts founded Women on Web in 2005 to support women living in countries where safe abortion was not available.

15. Women on Web provides access to both information and prescriptions for abortion pills to women living in countries where safe abortions are not available.

16. Women on Web has never provided prescriptions for abortion pills to women living in the United States.

17. Each year, Women on Web answers more than 120,000 emails from women around the world.

18. Plaintiff Aid Access ("*Aid Access*") is a Gesellshaft mit beshränkter Haftung ("*GmbH*") incorporated in Austria since December 2018.

19. Dr. Gomperts is the founder and Director of Aid Access.

20. Dr. Gomperts founded the website Aid Access to serve women with unwanted first trimester pregnancies globally in early 2018.

21. Aid Access and Dr. Gomperts have operated the web page "aidaccess.org."

22. As a licensed physician providing medical abortions to women in the United States, Dr. Gomperts brings this case on behalf of all her present and future pregnant patients seeking a medical abortion prior to viability who reside in the United States.

B. Defendants

23. Defendant Alex M. Azar, II, ("*Azar*"), who is being sued in his official capacity only as Secretary, United States Department of Health and Human Services ("*HHS*"), is

responsible for administering and enforcing the federal Food, Drug, and Cosmetic Act ("*FDCA*").

24. Defendant United States Food and Drug Administration ("*FDA*") is an agency of the United States Government within HHS and has offices in Washington D.C. and Silver Springs, Maryland. The Secretary of HHS has delegated to the FDA the authority to administer the relevant provisions of the FDCA.

25. Defendant Norman Sharpless ("*Sharpless*"), who is being sued in his official capacity only as the Acting Commissioner of Food and Drugs, is responsible for supervising the activities of the FDA. Defendant Sharpless maintains offices in Washington D.C. and Silver Springs, Maryland.

26. Defendant Janet Woodcock, M.D. ("*Woodcock*"), who is being sued in her official capacity only, is the Director of the Center for Drug Evaluation and Research ("*CDER*"). Defendant Woodcock, as the Director of the CDER, oversees various scientific and medical regulatory operations of the FDA. Defendant Woodcock maintains offices in Washington D.C. and Silver Springs, Maryland.

27. Defendant Thomas Christl ("*Christl*"), who is being sued in his official capacity only, was the Director of Drug Security, Integrity, and Response in the CDER, at least through the spring of 2019. Among the responsibilities of the Office of Drug Security, Integrity, and Response in the FDA's CDER is to ensure that drug importation and exportation adhere to federal laws and regulations. Defendant Christl maintained an office in Silver Springs, Maryland.

28. Defendant Ilisa Bernstein, ("*Bernstein*"), who is being sued in her official capacity only, is the current acting Director of Drug Security, Integrity, and Response in the CDER.

Among the responsibilities of the Office of Drug Security, Integrity, and Response in the FDA's CDER is to ensure that drug importation and exportation adhere to federal laws and regulations. Defendant Bernstein maintains an office in Silver Springs, Maryland.

FACTUAL ALLEGATIONS

A. FDA Restrictions on the Distribution of Mifepristone and Misoprostol

29. Since September of 2000, Misoprostol and mifepristone marketed in the United States under the name "Mifeprex" has been approved by the U.S. Food and Drug Administration ("*FDA*") to induce medical abortions during the early stages of pregnancies.

30. But, despite the strong findings on the safety and efficacy of misoprostol and mifepristone from the clinical trials and European post-marketing experience, the FDA only approved Mifeprix under a highly restricted distribution system as a condition of approval.

31. The restricted distribution system for Mifeprex imposed by the FDA is known as Risk Evaluation and Mitigation Strategy (REMS).

32. The FDA-approved REMS program for Mifeprex also included an Element to Assure Safe Use (ETASU) which has remained essentially unchanged since 2000.

33. Among the more significant restrictions imposed by the FDA on the distribution of Mifeprex under its REMS and ETASU programs are the following:

    a. Only healthcare providers who have been certified by Mifeprex's distributor may prescribe Mifeprex;

    b. To be certified to prescribe Mifeprex, the healthcare providers must attest that they have (1) the ability to date a pregnancy and diagnose an ectopic pregnancy, (2) made

plans for the patient to receive surgical abortion care in cases of incomplete abortion or severe bleeding, and (3) ensured that the patient has access to medical facilities equipped to provide blood transfusions and resuscitation, if necessary;

c. To be certified to prescribe Mifeprex, the healthcare provider must also agree to provide the patient with the Medication Guide and Patient Agreement, discuss the Patient Agreement with the patient, have the patient sign the Patient Agreement, and sign the Patient Agreement as well; and

d. Mifeprex may not be dispensed through any retail pharmacy. Instead, Mifeprex may only be dispensed in certain health care settings, specifically clinics, medical offices, and hospitals, by and under the supervision of a prescriber specially certified to prescribe Mifeprex as described above.

34. Despite the FDA's approval of Mifeprex almost 20 years ago, access to medical abortions for women in the early stages of pregnancy remains severely restricted in the United States.

35. The REMS and ETASU imposed by the FDA on Mifeprex has been and continues to be an undue burden on the rights of U.S. women to terminate their unwanted pregnancies during the early stages of their pregnancies.

36. Because of the high cost of in-clinic abortion services and the limited availability of misoprostol and mifepristone in the U.S. as a result of the REMS and ETASU imposed by the FDA on Mifeprex, many women in the U.S. have been forced to use the internet to obtain misoprostol and mifepristone to end their unwanted pregnancies.

37. Access to medical abortions is most restricted in geographically large and primarily rural states like Idaho where the number of physicians certified to prescribe Mifeprex is small.

38. The burden of these restrictions imposed by the FDA on medical abortions falls primarily on women who live in rural or medically underserved areas, have low income, are experiencing domestic abuse and/or are young.

39. Because women in Idaho are especially burdened by the FDA imposed restrictions on medical abortions, many women in Idaho have contacted Aid Access and Dr. Gomperts for help in ending their unwanted pregnancies prior to viability.

B. Aid Access and Dr. Gomperts.

40. Between March 30, 2018, and August 27, 2019, Aid Access has been contacted through its website forty thousand, six hundred ninety-one (40,691) times about medical abortions.

41. Since March 30, 2018, Dr. Gomperts -- through Aid Access – has consulted with women in *all* 50 states and the District of Columbia.

42. Between March 30, 2018, when Aid Access began accepting requests for assistance with unwanted pregnancies over the internet, and August 27, 2019, thirty-seven thousand, seventy-seven (37,077) women *in the U.S.* have contacted Aid Access.

43. Between March 30, 2018 and August 27, 2019, Dr. Gomperts has prescribed two medicines, *i.e.*, misoprostol and mifepristone, for seven thousand, one hundred thirty-one (7,131) of those women *in the U.S.*

44. Since March 30, 2018, one hundred twenty-seven (127) women *residing in Idaho* have contacted Aid Access and Dr. Gomperts has prescribed medicine (misoprostol and mifepristone) to induce a medical abortion of their pregnancies prior to viability for thirty-nine (39) of those women *residing in Idaho*.

45. Before women contacting Aid Access are prescribed medication (misoprostol and mifepristone) to induce a medical abortion, each woman's medical history is thoroughly reviewed by Dr. Gomperts.

46. If, after review of all the information available, Dr. Gomperts believes in her professional judgment as a licensed physician that the woman can safely have a medical abortion, Dr. Gomperts will provide that woman with a prescription for the appropriate dose of mifepristone and misoprostol with explicit and detailed instructions on how to safely take these medications.

47. The women prescribed mifepristone and misoprostol by Dr. Gomperts are provided instructions on how to get their prescriptions for misoprostol and mifepristone delivered to them in the U.S.

48. Dr. Gomperts' patients are directed to send their prescriptions to a merchant exporter of prescription medications in India, N N Agencies.

49. N N Agencies has been in business since 1997 and exports medicine to approximately one hundred (100) different countries including the U.S.

50. N N Agencies exports approximately one thousand, five hundred (1,500) different kinds of medicine from India.

51. N N Agencies only exports drugs which have been approved by "FDA India."

52. N N Agencies has been exporting prescription medication out of India for approximately two decades.

53. Under Indian law, N N Agencies is allowed to legally export small quantities of drugs for a patient's personal use.

54. To date, N N Agencies has never received any notice from the FDA or any other U.S. governmental agencies questioning their practices.

55. The source of the personal supply of mifepristone and misoprostol (M/s INTAS PHARMACEUTICALS LTD., BHAGHEY KHOLA, MAJHITAR, RANGO, EAST-SIRRAM – 737132) exported to Dr. Gomperts' patients holds a valid Drug Manufacturing License by the Government of Sikkem, India and has been certified as following Good Manufacturing Practices (GMP) in the manufacturing and testing of General Tablets and Capsules as per the World Health Organization (WHO) specifications. The WHO GMP CERTIFICATE is attached to the Complaint as "Exhibit A."

56. All forms required by the Customs and Border Protection and/or U.S. Postal Service are accurately and fully completed by N N Agencies prior to shipping the packages containing medicine to Dr. Gomperts' patients.

57. The Customs Declaration on the packages exported from India to Dr. Gomperts' patients in the U.S. accurately describe the contents of those packages as "Personal Supply of Rx Medicines."

C. FDA Letter

58. The FDA Warning Letter ("*FDA Letter*") addressed to "aidaccess.org" dated March 8, 2019, is attached to this Complaint as "Exhibit B."

59. The subject of the FDA Letter is shown as "Causing the Introduction of a Misbranded and Unapproved New Drug into Interstate Commerce."

60. According to the first sentence of the FDA Letter, Defendant FDA "recently reviewed your website, http://www.aidaccess .org, and determined that you caused the introduction

into interstate commerce of misbranded and unapproved new drugs in violation of sections 301(a), 301(d), and 505(a) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) [21 U.S.C. §§ 331(a), 331(d), and 355(a)]."

61. In the final section of the FDA Letter, Defendant Christl states that "[t]his letter is not intended to identify all the ways in which your activities might be in violation of U.S. law. You should promptly cease causing the sale of unapproved new drugs and misbranded drugs to U.S. consumers and correct all other violations of the FD&C Act."

62. The FDA Letter concluded with the following threat: "Failure to correct these violations may result in FDA regulatory action, including seizure or injunction, without further notice."

63. The FDA Letter addressed to Aidaccess.org is from Defendant FDA and was signed by Defendant Christl as the Director of the Office of Drug Security, Integrity, and Response, Office of Compliance, Center for Drug Evaluation and Research, Food and Drug Administration.

64. Dr. Gomperts is shown as having been cc'd on the FDA Letter.

65. The FDA letter dated March 8, 2019, caused Dr. Gomperts and Aid Access to temporarily discontinue providing medical abortions for women in the U.S. for almost two months, from March 17, 2019, until May 10, 2019.

66. Between March 17, 2019, and May 10, 2019, Dr. Gomperts and Aid Access were forced to deny help to hundreds of women in the U.S. who were seeking to terminate their pregnancies prior to viability.

67. Despite the risk to herself and her patients, Dr. Gomperts restarted providing medical abortions to women seeking to terminate their pregnancies prior to viability in the U.S. on May 10, 2019, and has continued to do so since then.

68. Since receiving the FDA Letter dated March 8, 2019, Dr. Gomperts believes that the FDA has seized between three and ten individual doses of misoprostol and mifepristone prescribed for between three and ten of her patients residing in the U.S. Dr. Gomperts' belief as to the number of packages likely seized by the FDA is based upon tracking information for the packages and communications from her patients.

69. Since receiving the FDA Letter dated March 8, 2019, transfers of funds between Dr. Gomperts and Aid Access and Dr. Gomperts' patients in the U.S. have been blocked on multiple occasions without explanation and Plaintiffs believe, based upon information and belief, that the blocking of these transfers between Dr. Gomperts and her patients has been at the direction of the FDA. (Patients have been blocked from using Moneygram, Xoom, Riamoneytransfer and XE to make payments to Aid Access).

70. After receiving the FDA Letter, Dr. Gomperts and Aid Access received notice from two business entities -- WorldRemit and Transferwise – previously used by Dr. Gomperts and Aid Access to transfer payments from Dr. Gomperts' patients in the U.S. that these businesses would no longer do business with Aid Access.

71. Because neither WorldRemit nor Transferwise offered any explanation as to why they were now refusing to transfer funds to Aid Access, Plaintiffs reasonably believe both did so at the suggestion or direction of the FDA or other agencies in the U.S. government.

72. Defendant Christl also signed a letter to counsel for Aid Access and Dr. Gomperts dated April 16, 2019, acknowledging receipt of counsel's letter requesting additional time to respond to the FDA Letter.

73. Counsel for Plaintiffs responded to the FDA Warning Letter on May 16, 2019. A copy of Plaintiffs' counsel's response ("*Plaintiffs' Response Letter*") is attached to this Complaint as "Exhibit C."

74. Sometime between April and August of 2019, Defendant Ilisa Bernstein became the acting Director of Drug Security, Integrity, and Response in the CDER.

75. As of the date of this Complaint, neither Defendants Christl nor Bernstein have formally responded to Plaintiffs' Response Letter dated May 16, 2019.

D. Indictment of Ursula Wing in the U.S District Court for the Western District of Wisconsin.

76. On June 26, 2019 -- less than six weeks after Plaintiffs' Response Letter was sent to the FDA -- Ursula Wing ("*Wing*") was indicted in the Western District of Wisconsin for importing foreign sourced versions of mifepristone and misoprostol into the U.S. for resale both inside and outside the U.S. A copy of the Ursula Wing Indictment is attached to the Complaint as "Exhibit D."

77. Wing was indicted for allegedly causing the introduction of foreign sourced versions of mifepristone and misoprostol, *i.e.*, misbranded and unapproved new drugs, into interstate commerce in violation of 21 U.S.C. § 331(a).

78. 21 U.S.C. §331(a) is the identical statute cited in the FDA Letter threatening Dr. Gomperts and Aid Access.

79. Based upon the seizure by the U.S. Department of Homeland Security, Customs and Border Protection and/or the U.S. Postal Inspection Service of three shipments of

allegedly misbranded misoprostol and mifepristone sent from India in 2018, Wing was also charged with conspiracy under 18 U.S.C. § 371.

80. According to the Ursula Wing Indictment, the U.S. Food and Drug Administration (FDA) is the federal agency charged with administering and enforcing the laws and regulations pertaining to the Federal Food, Drug and Cosmetic Act (FDCA).

81. According to the Ursula Wing Indictment, the U.S. Department of Homeland Security, Customs and Border Protection agency (CBP) is the federal agency charged with administering and enforcing the laws and regulations pertaining to the import and export of merchandise, including drugs, into and out of, the United States.

82. According to the Ursula Wing Indictment, whenever drugs falling under the jurisdiction of the FDA are declared or offered from import into the United States, the CBP notifies the FDA to determine whether the drug should be sampled and whether importation of the drug was lawful under the FDCA.

83. According to the Ursula Wing Indictment, the U.S. Postal Inspection Service (USPIS) is the federal agency charged with administering and enforcing the laws pertaining to the use of the U.S. mail.

84. In the FDA Letter addressed to Aid Access and cc'd to Dr. Gomperts, the FDA claims to have "determined that [Aid Access and Dr. Gomperts] cause the introduction into interstate commerce of misbranded and unapproved new drugs in violation of . . . 21 U.S.C. §§ 331(a), 331(d), and 355(a)."

85. Since receiving the FDA Letter dated March 8, 2019, Dr. Gomperts and Aid Access have had between three and ten of the packages containing misoprostol and mifepristone prescribed for between three and ten pregnant women in the U.S. seized by the U.S.

Department of Homeland Security, Customs and Border Protection and/or the U.S. Postal Inspection Service at the direction of the FDA.

86. The actual or threatened seizure of packages containing misoprostol and mifepristone prescribed by Dr Gomperts for pregnant women in the U.S. by the U.S. Department of Homeland Security, Customs and Border Protection and/or the U.S. Postal Inspection Service at the direction of the FDA as described above imposes significant burdens on Dr Gomperts' patients' access to abortions prior to viability that are not justified by the statutes' purported benefits and therefore impose an undue burden on those women's right to an abortion.

87. All of the packages containing medicine prescribed by Dr. Gomperts for pregnant women seeking medical abortions in the U.S. that have been seized by the U.S. Department of Homeland Security, Customs and Border Protection and/or the U.S. Postal Inspection Service at the direction of the FDA had been legally exported by N N Agencies from India.

88. If convicted of violating 21 U.S.C. § 331(a) "with the intent to defraud or mislead," Dr. Gomperts, like Wing, could "be imprisoned for not more than three years or fined not more than $10,000 or both" pursuant to 21 U.S.C. § 333(a)(2).

89. Pursuant to 18 U.S.C. § 371, Dr. Gomperts' patients in the U.S. seeking medical abortions may be prosecuted, like Wing is currently being prosecuted, by the federal government for conspiracy to violate 21 U.S.C. § 331(a).

90. Regardless of whether Dr. Gomperts' patients seeking medical abortions in the U.S. are ever prosecuted under federal law, those pregnant women identified as Dr. Gomperts'

patients by CBP and/or USPIS could be subjected to prosecution under state law by state prosecutors in the states where they reside.

91. The threat of criminal charges being filed against Dr. Gomperts and/or her patients as described above imposes significant burdens on Dr Gomperts' patients' access to abortions prior to viability that are not justified by the statutes' purported benefits and therefore impose an undue burden on those women's right to an abortion.

CLAIMS FOR RELIEF

COUNT I
(Substantive Due Process – Patients' Right to Privacy)

92. The allegations contained in paragraphs 1 through 91 above are incorporated as though fully set forth herein.

93. The seizing of medicine prescribed by Dr. Gomperts for women in the U.S. who are seeking to terminate their unwanted pregnancies prior to viability by the FDA or other federal agencies at the FDA's direction as threatened in the FDA Letter dated March 8, 2019, violates Dr. Gomperts and her U.S. patients' rights to liberty and privacy as guaranteed by the due process clause of the Fifth Amendment to the U.S. Constitution by imposing significant burdens on the rights of those women who chose -- in consultation with their physician -- to terminate their pregnancies, thereby imposing an undue burden on those women's right to abortion.

94. The blocking of transfers of funds between Dr. Gomperts' patients and Dr Gomperts and/or Aid Access by the FDA or other federal agencies at the FDA's direction as threatened in the FDA Letter dated March 8, 2019, violates Dr. Gomperts' U.S. patients' rights to liberty and privacy as guaranteed by the due process clause of the Fifth

Amendment to the U.S. Constitution, thereby imposing an undue burden on those women's right to abortion.

95. The prosecution of Dr. Gomperts and/or any of her patients in the United States under 21 U.S.C. §§ 331(a) and/or 331(d) would violate Dr. Gomperts and her U.S. patients' rights to liberty and privacy as guaranteed by the due process clause of the Fifth Amendment to the U.S. Constitution by imposing significant burdens on the rights of those women who chose -- in consultation with their physician -- to terminate their pregnancies, thereby imposing an undue burden on those women's right to abortion.

96. The prosecution of Dr. Gomperts and any of her patients in the United States under 18 U.S.C § 371 for conspiring to violate 21 U.S.C. §§ 331(a) and/or 331(d) would violate Dr. Gomperts and her U.S. patients' rights to liberty and privacy as guaranteed by the due process clause of the Fifth Amendment to the U.S. Constitution by imposing significant burdens on the rights of those women who chose -- in consultation with their physician -- to terminate their pregnancies, thereby imposing an undue burden on those women's right to abortion.

COUNT II
(Equal Protection)

97. The allegations contained in paragraphs 1 through 96 above are incorporated as though fully set forth herein.

98. The seizing of medicine prescribed by Dr. Gomperts for women in the U.S. who are seeking to terminate their unwanted pregnancies during the early stages of those pregnancies by the FDA or other federal agencies at the FDA's direction as threatened in the FDA Letter dated March 8, 2019, violates Dr. Gomperts' U.S. patients' right to equal protection under the Fifth Amendment to the United States Constitution by treating Dr.

Gomperts' patients differently from other similarly situated parties without a sufficient state interest.

99. The blocking of transfers of funds between Dr. Gomperts' patients and Dr Gomperts and/or Aid Access by the FDA or other federal agencies at the FDA's direction as threatened in the FDA Letter dated March 8, 2019, violates Dr. Gomperts' U.S. patients' rights to equal protection under the Fifth Amendment to the United States Constitution by treating Dr. Gomperts and her patients differently from other similarly situated parties without a sufficient state interest.

100. The prosecution of Dr. Gomperts and/or any of her patients in the United States under 21 U.S.C. §§ 331(a) and/or 331(d) would violate Dr. Gomperts' and her U.S. patients' right to equal protection under the Fifth Amendment to the United States Constitution by treating Dr. Gomperts and her patients differently from other similarly situated parties without a sufficient state interest.

101. The prosecution of Dr. Gomperts and any of her patients in the United States under 18 U.S.C § 371 for conspiring to violate 21 U.S.C. §§ 331(a) and/or 331(d) would violate Dr. Gomperts' and her U.S. patients' right to equal protection under the Fifth Amendment to the United States Constitution by treating Dr. Gomperts and her patients differently from other similarly situated parties without a sufficient state interest.

COUNT III

(Administrative Procedures Act – Contrary to Constitutional Right)

102. The allegations contained in paragraphs 1 through 101 above are incorporated as though fully set forth herein.

103. The FDA Letter and other agency action and inaction described herein constituted final agency action for which Dr. Gomperts and/or Dr. Gomperts' patients have no other adequate remedy within the meaning of 5 U.S.C. § 704.

104. The FDA Letter and other agency action and inaction described herein is contrary to Dr. Gomperts' and/or Dr. Gomperts' patients' constitutional rights, including their rights under the Fifth Amendment to the U.S. Constitution in violation of 5 U.S.C. § 706(2)(B).

COUNT IV
(Administrative Procedures Act – In Excess of Statutory Authority)

105. The allegations contained in paragraphs 1 through 104 above are incorporated as though fully set forth herein.

106. The FDA Letter and other agency action and inaction described herein constituted final agency action for which Dr. Gomperts and/or Dr. Gomperts' patients have no other adequate remedy within the meaning of 5 U.S.C. § 704.

107. The FDA Letter and other agency action and inaction described herein is in excess of the FDA's statutory authority under the FDCA in violation of 5 U.S.C. 706(2)(C).

COUNT V
(Administrative Procedures Act – Arbitrary, Capricious and Abuse of Discretion)

108. The allegations contained in paragraphs 1 through 107 above are incorporated as though fully set forth herein.

109. The FDA Letter and other agency action and inaction described herein constituted final agency action for which Dr. Gomperts and/or Dr. Gomperts' patients have no other adequate remedy within the meaning of 5 U.S.C. § 704.

110. The FDA Letter and other agency action and inaction described herein treated similarly treated physicians and their patients differently without justification and therefore was arbitrary, capricious, an abuse of discretion and otherwise not in accordance with law in violation of 5 U.S.C. § 706(2)(A).

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request that the Court enter judgement in their favor and

1) Declare, pursuant to 28 U.S.C. § 2201, that the seizing of medicine prescribed by Dr. Gomperts for women in the U.S. who seek her assistance as a licensed physician in terminating their unwanted pregnancies during the early stages of those pregnancies by the FDA or other federal agencies at the FDA's direction as threatened in the FDA Letter dated March 8, 2019, violates Dr. Gomperts' U.S. patients' rights to liberty and privacy as guaranteed by the due process clause of the Fifth Amendment to the U.S. Constitution.
2) Declare, pursuant to 28 U.S.C. § 2201, that the blocking of transfers of funds between Dr. Gomperts' patients and Dr Gomperts and/or Aid Access by the FDA or other federal agencies at the FDA's direction as threatened in the FDA Letter dated March 8, 2019, violates Dr. Gomperts' U.S. patients' rights to liberty and privacy as guaranteed by the due process clause of the Fifth Amendment to the U.S. Constitution.
3) Declare, pursuant to 28 U.S.C. § 2201, that the prosecution of Dr. Gomperts and/or her U.S. patients who seek her assistance as a licensed physician in terminating their unwanted pregnancies during the early stages of those pregnancies under 21 U.S.C. § 331(a) and/or 21 U.S.C. § 331(d) or the prosecution of Dr. Gomperts and/or her U.S. patients under 18 U.S.C. § 371 for conspiracy to violate 21 U.S.C. § 331(a) and/or 21 U.S.C. § 331(d) would

violate Dr. Gomperts' and her U.S. patients' rights to liberty and privacy as guaranteed by the due process clause of the Fifth Amendment to the U.S. Constitution.

4) Declare, pursuant to 28 U.S.C. § 2201, that the seizing of medicine prescribed by Dr. Gomperts for women in the U.S. who seek her assistance as a licensed physician in terminating their unwanted pregnancies during the early stages of those pregnancies by the FDA or other federal agencies at the FDA's direction as threatened in the FDA Letter dated March 8, 2019, violates Dr. Gomperts' U.S. patients' right to equal protection under the Fifth Amendment to the United States Constitution by treating Dr. Gomperts and her patients differently from other similarly situated parties without a sufficient state interest.

5) Declare, pursuant to 28 U.S.C. § 2201, that the blocking of transfers of funds between Dr. Gomperts' patients and Dr Gomperts and/or Aid Access by the FDA or other federal agencies at the FDA's direction as threatened in the FDA Letter dated March 8, 2019, violate Dr. Gomperts' U.S. patients' right to equal protection under the Fifth Amendment to the United States Constitution by treating Dr. Gomperts and her patients differently from other similarly situated parties without a sufficient state interest.

6) Declare, pursuant to 28 U.S.C. § 2201, that the prosecution of Dr. Gomperts and/or her U.S. patients who seek her assistance as a licensed physician in terminating their unwanted pregnancies during the early stages of those pregnancies under 21 U.S.C. § 331(a) and/or 21 U.S.C. § 331(d) or the prosecution of Dr. Gomperts and/or her U.S. patients under 18 U.S.C. § 371 for conspiracy to violate 21 U.S.C. § 331(a) and/or 21 U.S.C. § 331(d) would violate Dr. Gomperts' U.S. patients' right to equal protection under the Fifth Amendment to the United States Constitution by treating Dr. Gomperts and her patients differently from other similarly situated parties without a sufficient state interest.

7) Declare, pursuant to 28 U.S.C. § 2201, that the FDA Letter and other agency action and inaction described herein violates the Administrative Procedures Act.

8) Enter an injunction prohibiting Defendants, their employees, agents and successors in office, from taking any action, directly or indirectly through another federal agency, that would impede or delay the delivery of misoprostol and mifepristone prescribed by Dr. Gomperts to her patients in the United States.

9) Enter an injunction prohibiting Defendants, their employees, agents and successors in office, from taking any action, directly or indirectly through another federal agency, that would cause criminal charges to be brought against Dr. Gomperts and/or Aid Access and/or Dr. Gomperts' patients based upon Dr. Gomperts' prescribing of misoprostol and mifepristone for her patients seeking to terminate their pregnancies prior to viability in the United States.

10) Enter a preliminary injunction prohibiting Defendants, their employees, agents and successors in office, from taking any action, directly or indirectly through another federal agency, that would impede or delay the delivery of misoprostol and mifepristone prescribed by Dr. Gomperts to her patients seeking to terminate their pregnancies prior to viability in the United States.

11) Enter a preliminary injunction prohibiting Defendants, their employees, agents and successors in office, from taking any action, directly or indirectly through another federal agency, that would cause criminal charges to be brought against Dr. Gomperts and/or Aid Access and/or Dr. Gomperts' patients based upon Dr. Gomperts' prescribing of misoprostol and mifepristone for her patients seeking to terminate their pregnancies prior to viability in the United States.

12) Award to Plaintiffs costs, expenses, and attorneys' fees pursuant to 28 U.S.C. § 2412; and

13) Award such other, further, and different relief as the court deems just and proper.

[Signatures on following page]

DATED this 8 day of September, 2019.

RICHARD A. HEARN
HEARN LAW, PLC

DATED this 8 day of September, 2019.

REBECCA GOMPERTS

DATED this 8 day of September, 2019.

REBECCA GOMPERTS, Director
Aid Access

EXHIBIT A

GOVERNMENT OF SIKKIM
DEPARTMENT OF HEALTH CARE, HUMAN SERVICES & FAMILY WELFARE
(DRUGS AND COSMETICS CELL)
TADONG - GANGTOK

Certificate No: ***10/WHO-GMP/DC/SKM*** Date: ***18/07/2018***

WHO GMP CERTIFICATE

This is to certify that ***M/s INTAS PHARMACEUTICALS LTD., BHAGHEY KHOLA, MAJHITAR, RANGPO, EAST-SIKKIM - 737132,*** is holding valid Drug Manufacturing License in **Form 25** bearing License no. **M/517/09** and **Form 28** bearing License No. **M/516/09** and **Form 25-F** bearing license no. **M/548/10** issued by this administration under the provisions of Drugs and Cosmetics Act, 1940 and Rules there under. Under the said licenses the firm is permitted to manufacture and sell their products under the categories of ***General Tablets, (Coated & Uncoated) & Capsules.***

The firm has employed competent persons in manufacturing and Quality Control Departments. The firm is following Good Manufacturing Practices (GMP) in the manufacturing and testing of the above mentioned categories of formulations as per World Health Organization (WHO) specifications. The manufacturing plant is subject to regular inspections by the competent authority under the Act.

This certificate is valid up to ***17/07/2021.***

DRUGS & COSMETICS CELL • DEPTT. OF HC, HS & FW •

LICENSING AUTHORITY
LICENSING AUTHORITY
Drugs & Cosmetics Cell
HC,HS & FW Deptt.
Govt. of Sikkim

EXHIBIT B

U.S. FOOD & DRUG ADMINISTRATION

TO: Aidaccess.org

FROM: The United States Food and Drug Administration

RE: Causing the Introduction of a Misbranded and Unapproved New Drug into Interstate Commerce

DATE: March 8, 2019

WARNING LETTER

The United States (U.S.) Food and Drug Administration (FDA) recently reviewed your website, http://www.aidaccess.org, and determined that you cause the introduction into interstate commerce of misbranded and unapproved new drugs in violation of sections 301(a), 301(d), and 505(a) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) [21 U.S.C. §§ 331(a), 331(d), and 355(a)].

The sale of misbranded and unapproved new drugs poses an inherent risk to consumers who purchase those products. Unapproved new drugs do not have the same assurance of safety and effectiveness as those drugs subject to FDA oversight. Drugs that have circumvented regulatory safeguards may be contaminated, counterfeit, contain varying amounts of active ingredients, or contain different ingredients altogether.

FDA requests that you immediately cease causing the introduction of these violative drugs into U.S. commerce.

Unapproved New Drug

Aidaccess.org states on its website, "Aid Access supports women who are not able to access local services. If you are healthy and less than 9 weeks pregnant, you can do the online consultation. The abortion pills mifepristone and misoprostol will be delivered to you by mail." By facilitating the sale of unapproved mifepristone and misoprostol to consumers in the U.S., Aidaccess.org causes the introduction of unapproved new drugs into U.S. commerce in violation of the FD&C Act. These products are drugs within the meaning of section 201(g) of the FD&C Act [21 U.S.C. § 321(g)] because they are intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease and/or because they are intended to affect the structure or function of the body. These drugs are also new drugs as defined by section 201(p) of the FD&C Act [21 U.S.C. § 321(p)], because they are not generally recognized as safe and effective for their labeled use. New drugs may not be legally introduced or delivered for introduction into interstate commerce without prior approval from FDA, as described in section 505(a) of the FD&C Act [21 U.S.C. § 355(a)].

Aidaccess.org facilitates the sale to U.S. consumers of unapproved mifepristone in a regimen with unapproved misoprostol labeled for the termination of pregnancy, including "a-Kare," a combination pack that includes both mifepristone and misoprostol tablets. The "a-Kare" product is labeled as a "Combipack of Mifepristone Tablets IP & Misoprostol Tablets IP" and is manufactured by Synokem Pharmaceuticals Ltd. (Synokem). The patient insert accompanying the product states that "a-Kare" is "indicated for early medical abortion for up to 9 weeks." The product labeling states that "a-Kare" is "Marketed by: DKT India."

No approved applications pursuant to section 505 of the FD&C Act are in effect for this product. Accordingly, its introduction or delivery for introduction into interstate commerce violates sections 301(d) [21 U.S.C. § 331(d)] and 505(a) [21 U.S.C. § 355(a)] of the FD&C Act.

There is an FDA-approved prescription mifepristone drug product that is marketed in the U.S. under the brand name "Mifeprex" and indicated in a regimen with FDA-approved misoprostol, for the termination of early pregnancy (10 weeks or less since last menstrual period began). However, there are no approved drug applications pursuant to section 505 of the FD&C Act in effect for the "a-Kare" product manufactured by Synokem, caused to be introduced into U.S. commerce via Aidaccess.org.

The substitution of unapproved drugs for FDA-approved prescription drugs poses significant health risks to U.S. consumers. For example, in this case, use of the unapproved drug would not be subject to the same protections as use of the FDA-approved product. Mifeprex labeling bears a boxed warning indicating that the drug carries a risk of serious or even life-threatening adverse effects, including serious and sometimes fatal infections and prolonged heavy bleeding, which may be a sign of incomplete abortion or other complications. As further noted in the Mifeprex labeling, Mifeprex is only available in the U.S. through a Risk Evaluation and Mitigation Strategy (REMS) program. The REMS program is intended to mitigate the risk of serious complications associated with Mifeprex by: requiring healthcare providers who prescribe Mifeprex to be certified in the Mifeprex REMS program; ensuring that Mifeprex is only dispensed in certain healthcare settings by or under the supervision of a certified prescriber; and informing patients about the risk of serious complications associated with Mifeprex. Consistent with the REMS, Mifeprex is not sold through retail pharmacies or over the internet. Use of the unapproved "a-Kare" product would not be subject to these FDA-approved REMS provisions.

Misbranded Drug

A drug is misbranded under section 502(f)(1) of the FD&C Act [21 U.S.C. § 352(f)(1)] if it fails to bear adequate directions for its intended use(s). "Adequate directions for use" means directions under which a layperson can use a drug safely and for the purposes for which it is intended (21 CFR 201.5). Prescription drugs, as defined in section 503(b)(1) of the FD&C Act [21 U.S.C. § 353(b)(1)], include those that, because of their toxicity or other potentiality for harmful effect, and/or the method of their use, and/or the collateral measures necessary for their use, are not safe for use except under supervision of a practitioner licensed by law to administer them. Prescription drugs, as defined in section 503(b)(1)(A) of the FD&C Act, can only be used safely at the direction, and under the supervision, of a licensed practitioner.

Because the "a-Kare" product contains prescription drugs intended for a condition that is not amenable to self-diagnosis and treatment by a layperson, adequate directions cannot be written such that a layperson can use the product safely for its intended use. Consequently, the labeling for "a-Kare" fails to bear adequate directions for its intended use, causing it to be misbranded under section 502(f)(1) of the FD&C Act. In addition, because "a-Kare" is not approved in the U.S., it is also not exempt under 21 CFR 201.115(a) from the requirements of section 502(f)(1) of the FD&C Act.

The "a-Kare" product is also misbranded under section 502(f)(2) of the FD&C Act [21 U.S.C. § 352(f)(2)] because it fails to bear "adequate warnings against use...where its use may be dangerous to health, or against unsafe dosage

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or methods or duration of administration or application...." This is particularly concerning because FDA-approved mifepristone indicated for medical termination of early pregnancy is subject to a REMS program. The REMS program for Mifeprex restricts dispensing to certain healthcare settings, specifically clinics, medical offices, and hospitals, by or under the supervision of a certified prescriber. Healthcare providers who prescribe Mifeprex must be certified in the Mifeprex REMS program. In order to be certified, the prescriber must have the ability to: assess the duration of the pregnancy accurately, diagnose ectopic pregnancies, and provide surgical intervention in cases of incomplete abortion or severe bleeding, or to have made arrangements for others to provide such care. Healthcare providers must be able to ensure that women have access to medical facilities for emergency care, and must agree to other responsibilities, including reviewing and signing the Patient Agreement Form with the patient and providing each patient with a copy of the signed Patient Agreement Form and the Medication Guide. In addition, the REMS program contains specific requirements for distributors including, but not limited to, following processes and procedures for storage, handling, shipping, tracking package serial numbers, proof of delivery and controlled returns of Mifeprex. By facilitating the sale of the unapproved and misbranded "a-Kare" product, Aidaccess.org is causing important safety measures that are put in place for FDA-approved mifepristone for medical termination of early pregnancy to be bypassed.

By facilitating the sale of "a-Kare" to U.S. consumers, Aidaccess.org is causing the introduction of a misbranded drug into interstate commerce in violation of section 301(a) of the FD&C Act [21 U.S.C. § 331(a)].

* * *

FDA is taking this action against Aidaccess.org because of the risks posed by its conduct in causing the introduction of a misbranded and unapproved new drug into U.S. commerce. FDA's regulation and oversight of the drug approval process protects consumers by requiring rigorous scientific standards for new drug approval, labeling review for accuracy and completeness, and manufacturing procedures and testing performed under closely controlled conditions at FDA-registered and inspected facilities. Sourcing drugs from outside of the legitimate U.S. drug supply chain can pose serious risks to patients who may receive medications that are adulterated and are not shipped and/or stored properly.

This letter is not intended to identify all the ways in which your activities might be in violation of U.S. law. You should promptly cease causing the sale of unapproved new drugs and misbranded drugs to U.S. consumers and correct all other violations of the FD&C Act. Failure to correct these violations may result in FDA regulatory action, including seizure or injunction, without further notice.

Please notify this office in writing within 15 working days of receipt of this letter of any steps you have taken or will take to correct the violations set forth above and to prevent their recurrence. If the corrective action(s) cannot be completed within 15 working days, state the reason for the delay and the time within which the correction(s) will be completed. If you believe that this product is not in violation of the FD&C Act, include your reasoning and any supporting information for our consideration.

U.S. Food and Drug Administration
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Silver Spring, MD 20903
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Your response and any other inquiries concerning this letter should be sent to FDA's Internet Pharmacy Task Force at FDAInternetPharmacyTaskForce-CDER@fda.hhs.gov.

Sincerely,

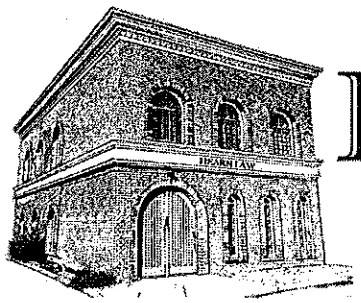
Thomas Christl
Director
Office of Drug Security, Integrity, and Response
Office of Compliance
Center for Drug Evaluation and Research
Food and Drug Administration

Cc:

Dr. Rebecca Gomperts
Synokem Pharmaceuticals Ltd.
DKT India (affiliate of DKT International, USA)

U.S. Food and Drug Administration
10903 New Hampshire Ave
Silver Spring, MD 20903
www.fda.gov

EXHIBIT C



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Richard A. Hearn, M.D., J.D.
John B. Ingelstrom, J.D.
John J. Bulger, J.D.
A. Bruce Larson, J.D.

May 14, 2019

Thomas Christl
Director
Office of Drug Security, Integrity, and Response
Center for Drug Evaluation and Research
Food and Drug Administration

Sent via email: FDAInternetPharmacyTaskForce-CDER@fda.hhs.gov

RE: Warning Letter to Aidaccess.org and Dr. Rebecca Gomperts dated March 8, 2019

Mr. Christl:

INTRODUCTION

The effect, if not the purpose, of the Warning Letter sent to Dr. Gomperts and Aidaccess.org has been to place a substantial burden in the path of U.S. women seeking to terminate their pregnancies prior to viability. In other words, the Warning Letter violates the constitutional rights of Dr. Gomperts' patients in the U.S. Because access to medical abortions in the U.S. has been so restricted by the Food and Drug Administration (FDA), women have been forced to attempt to exercise their right to a medical abortion by way of the internet.

In the face of more than 17,000 drug overdose deaths from opioids in the U.S. in 2017 – most of which were related to fentanyl illicitly sent by mail into the U.S. from China, and the tens of thousands of other harms to women caused by other drugs and medical devices (e.g., Essure, surgical mesh, breast implants) -- the Food and Drug Administration has decided to target a physician in Austria using telemedicine to provide constitutionally protected access to medical abortions in the United States. Medical abortions have the same mortality rate as natural miscarriages, (approximately 1 death per

234,000 prescriptions)[1]. That means that medical abortions are significantly safer than natural childbirth, (1 death per 3,788 births),[2] penicillin (1 death per 100,000 prescriptions) [3] and Viagra (1 death per 20,000 prescriptions)[4]. The National Academies of Sciences, Engineering, and Medicine reported that risks are similar in magnitude to the reported risks of serious adverse effects of commonly used prescription and over-the-counter medications.[5]

Women in the U.S. have a 60-fold higher risk of death from childbirth than from a medical abortion.

Safety concerns simply cannot justify the FDA's Warning Letter.

A. Dr. Gomperts and Aid Access.

Rebecca Gomperts is a physician licensed to practice medicine in Austria. She studied medicine in Amsterdam, the Netherlands. In 2011, she completed her Master's in Public Policy at Princeton University and, in 2014, she completed her PhD at the Karolinska Institute. Dr. Gomperts is the founder and Director of Women on Waves and Women on Web.

In response to a growing number of help-request from women around the world, Dr. Gomperts founded an online medical abortion service, Women on Web, in 2005. The service supports women living in countries where safe abortion is not available. Women on Web allows women in these countries to obtain information and access to abortion pills. The Women on Web helpdesk answers more than 100,000 emails from women around the world every year. But Women on Web has never attempted to serve women seeking medical abortions in the United States. Many scientific studies of the outcome of the abortions and the experiences of women using telemedical abortion services have proven that this is very safe, very effective and highly acceptable for women.[6]

In 2018, Dr. Gomperts started Aid Access to also serve women with unwanted first trimester pregnancies seeking medical abortions in the U.S. During the last 10 months of 2018, Dr. Gomperts consulted with women in all 50 states and the District of Columbia. Of the 11,108 women in the U.S. who consulted Dr.Gomperts in 2018, 2,581 were prescribed medicine approved by the FDA to induce a medical abortion for early abortions. These prescriptions have all been filled by a pharmacy in India. Neither Dr. Gomperts nor Aid Access have any ownership interest in or control over the Indian pharmacy. Aid Access is a Gesellshaft mit beschränkter Haftung ("*GmbH*") incorporated in Austria.[7]

Dr. Gomperts is not aware of a single death, hospitalization or serious complication attributed to the prescriptions she prescribed for her patients in the U.S. In fact, many of Dr. Gomperts' patients have expressed their appreciation for the medical services they were provided through Aid Access.[8]

Neither Dr. Gomperts nor Aid Access manufacture or dispense prescription medication. Nor does Dr. Gomperts import or export prescription medications to or from any country including the United States.

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[1] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3711556/

[2] https://www.thelancet.com/pdfs/journals/lancet/PIIS0140-6736(16)31470-2.pdf.

[3] http://jac.oxfordjournals.org/content/60/5/1172.long

[4] Mitka, Mike. (2000) Some Men Who Take Viagra Die? Why? Journal of the American Medical Association (283)5: 590-593.

[5] https://www.nap.edu/read/24950/chapter/4#58

[6] M Endler *et al*, Telemedicine for medical abortion: a systematic review, BJOG: 14 March 2019.

[7] A GmbH in Austria is roughly equivalent to a limited liability corporation in the United States.

[8] *See* Exhibit A to this letter for quotes from correspondence received from Dr. Gomperts' patients.

The fact that the FDA is now alleging that Dr. Gomperts' treatment of U.S. patients seeking to terminate their pregnancies prior to viability by way of telemedicine violates FDA statutes regulating the marketing of prescription medication by drug manufacturers to physicians is quite extraordinary.

B. The FDA Lacks Jurisdiction Over Dr. Gomperts' Practice of Medicine.

In your March 8, 2019, Warning Letter, you claim that the "United States (U.S.) Food and Drug Administration (FDA) recently reviewed [Dr. Gomperts'] website, http://www.aidaccess.org, and determined that [Dr. Gomperts] cause[d] the introduction into interstate commerce of misbranded and unapproved new drugs in violation of sections 301(a), 301(d), and 505(a) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) [21 U.S.C. §§ 331(a), 331(d), and 355(a)]."[9] Dr. Gomperts has never "caused" anyone to introduce or deliver any drug or article into interstate commerce in violation of U.S. law.

Your claim that the writing of a prescription by Dr. Gomperts violates the FD&C Act [21 USCS §§ 331 et. seq.] by causing "the introduction into interstate commerce of misbranded and unapproved new drugs" is not only factually incorrect, but is explicitly precluded by FDA positions on the "practice of medicine," the permissiveness of FDA's attitudes on "off label use," and the need for recognition of the first amendment speech rights of physicians.[10]

> While physicians are free to prescribe drugs for off-label uses, [physicians] rely on the FDA-approved prescribing information to determine which drugs can be used safely and effectively by patients with specific health problems.[11]

The Warning Letter sent to Dr. Gomperts appears to have been a blatant attempt by the FDA to deter Dr. Gomperts from providing her patients with necessary medical care based on her sound understanding of the medical situation and needs of her patients.

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[9] *21 U.S.C. §§ 331(a)* and *(d)* referenced in your letter states that "[t]he following acts and the causing thereof are hereby prohibited:
(a) The introduction or delivery for introduction into interstate commerce of any food, drug, device, tobacco product, or cosmetic that is adulterated or misbranded.
. . .
(d) The introduction or delivery for introduction into interstate commerce of any article in violation of section 404, 415, 505, or 564 [21 USC § 344, 350d, 355, or 360bbb-3].

21 U.S.C. § 355(a) also referenced in your letter states that "[n]o person shall introduce or deliver for introduction into interstate commerce any new drug, unless an approval of an application filed pursuant to subsection (b) or (j) is effective with respect to such drug."

[10] W Teo, FDA and the Practice of Medicine: Looking at Off-Label Drugs, Seaton Hall Legislative Journal, Vol 41:2; https://pdfs.semanticscholar.org/e1fb/a8e8a0e52a1f3776b44e9cf2c6f8b5c359dd.pdf

[11] *Hartman v. Gilead Scis., Inc. (In re Gilead Scis. Sec. Litig.)*, 536 F.3d 1049, 1051 (9th Cir. 2008) (*citing 21 U.S.C. § 396; Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 350-51, 121 S. Ct. 1012, 148 L. Ed. 2d 854 & n.5 (2001) (explaining that "[ ] the FDA is charged with the difficult task of regulating the marketing and distribution of medical devices without intruding upon decisions statutorily committed to the discretion of health care professionals")); *See also*, Coleen Klasmeier and Martin Redish, Off-Label Prescription Advertising, the FDA and the First Amendment: A Study in the Values of Commercial Speech Protection, 37 Am. J. L. and Med. 315 (2011).

No U.S. court has ever held that a physician violates any of the statutes cited in your letter simply by writing a prescription which was subsequently filled by a pharmacy. Furthermore, the prescriptions written by Dr. Gomperts were for misoprostol and mifepristone which are prescription drugs approved for medical abortions by the FDA. Neither misoprostol nor mifepristone are controlled substances like opioids regulated by the Drug Enforcement Agency.

A prescription for an FDA approved medication written by a licensed physician cannot possibly be the legal cause of that medication being introduced into interstate commerce in the United States.[8] The fact that U.S. citizens sought medical care from Dr. Gomperts in Austria through her webpage, Aidaccess.org, and Dr. Gomperts prescribed medication for those U.S. citizens who consulted her in Austria does not confer jurisdiction on the U.S. Food and Drug Administration over Dr. Gomperts' practice of medicine in Austria.

Because misoprostol and mifepristone are intended for use to terminate a pre-viability pregnancy, the FDA states (not necessarily accurately) that "adequate directions cannot be written such that a layperson can use the product safely for its intended use."[12] And, according to the FDA, because adequate directions cannot be written for the use of these drugs to terminate a pre-viability pregnancy, misoprostol and mifepristone are "[p]rescription drugs, as defined in section 503(b)(1)(A) of the FD&C Act, [and, according to the FDA] can only be used safely at the direction, and under the supervision, of a licensed physician."[13]

Dr. Gomperts is a licensed physician and her patients use these drugs to terminate their pregnancies – not as laypersons according to any directions contained in the drug packaging – but instead "at the direction, and under the supervision, of" Dr. Gomperts.[14]

"A drug is misbranded under section 502(f)(1) of the FD&C Act [21 U.S.C. § 352(f)(1)] if it fails to bear adequate directions for its intended use."[15] But, because misoprostol and mifepristone are prescription drugs, the purpose of the "directions for use" for these drugs is to provide essential information to Dr. Gomperts so that she can use the drugs safely and effectively in the care of her patients. The "directions for use" of a prescription drug is not for the benefit of the patient, but instead, for the benefit of the prescribing doctor.

The distinction between the directions for use requirement for prescription drugs and non-prescription drugs was set out by the Fifth Circuit in *United States v. Evers*.

> Where non-prescription drugs are involved, the "adequate directions for use" requirement insures full disclosure to the layman purchasing the drugs for self-treatment. But prescription drugs depend for their safety and effectiveness on the professional judgment of a licensed physician. Accordingly, the prescription drug exceptions to the "adequate directions for use" requirement contain conditions requiring adequate information for

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[12] The FDA -- and not Dr. Gomperts -- introduced mifepristone and misoprostol for the termination of pre-viability pregnancies into interstate commerce in the United States in 2000. As noted on page two of your original letter to Dr. Gomperts,"[t]here is an FDA-approved prescription mifepristone drug product that is marketed in the U.S. under the brand name "Mifeprex" and indicated in a regimen with FDA approved misoprostol, for the termination of early pregnancy (10 weeks or less since last menstrual period began)

[13] FDA Warning Letter dated March 8, 2019 ("*Warning Letter*"), p 2.

[14] *Id.*

[15] *Id.*

prescribing doctors. As the FDA has itself explained in a notice of proposed rulemaking:

> The primary objective of prescription drug **labeling** is to provide the essential information the practitioner needs to use the drug safely and effectively in the care of patients.

40 Fed. Reg. 15392 (1975) (*emphasis added*). The distributor of a non-prescription drug must provide adequate information for use by a layman, for patients are allowed to administer those drugs without the advice of a physician. The distributor of a prescription drug, however, must provide adequate information to the prescribing physician in accordance with the specific conditions of the statutory or regulatory exceptions to section 502(f) (1), for it is the physician who bears the responsibility for dispensing the drug. *See* D. A. Kessler, supra, at 742, 747; H. A. Toulmin, Jr., A Treatise on the Law of Foods, Drugs & Cosmetics § 24.12 at 576 (2d ed. 1963).[16]

Dr. Gomperts has never facilitated or caused any misbranded prescription drugs to be introduced into interstate commerce in the U.S. because no allegedly misbranded drugs with inadequate directions for use were ever distributed to any physician or doctor in the U.S.

As it is generally accepted that the FDA has no authority over the practice of medicine by licensed doctors in the U.S., it is surprising that the FDA would now be claiming to have authority over the practice of medicine by a licensed doctor in Austria.[17] Perhaps even more surprising is the fact that the FDA has chosen to test its new and expanded claim of authority to include regulating the practice of medicine on Dr. Gomperts and her patients seeking medical abortions. As discussed below, the FDA's statutory authority to regulate drug manufacturers cannot be used to deny women their constitutional right to terminate their pregnancies pre-viability.

C. The FDA Is Unduly Burdening Dr. Gomperts' Patients' Constitutional Right to a Pre-Viability Abortion.

Conspicuously absent from the FDA's Warning Letter is any mention of the constitutional rights of Dr. Gomperts' patients to a pre-viability abortion. The right of a woman to terminate a pregnancy prior to viability is guaranteed in the U.S. Constitution. Unfortunately, many women in the U.S. can only exercise that right by seeking medical care from Dr. Gomperts.

As you stated in the Warning Letter, "Mifeprex [misoprostol and mifepristone] is only available in the U.S. through a Risk Evaluation and Mitigation Strategy (REMS) program."[18] Regardless of the purpose of the FDA in placing Mifeprex in the REMS program, the effect of the Mifeprex REMS is to unduly burden U.S. women seeking to terminate their pregnancies before the fetus obtains viability. The American College of Obstetricians and

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[16] *United States v. Evers*, 643 F.2d 1043, 1052 (5th Cir. 1981).

[17] *See* James M. Beck and Elizabeth D. Azari, FDA, Off-Label Use, and Informed Consent: Debunking Myths and Misconceptions, 53 Food Drug L.J. 71,*76 (1998) ("FDA never has had authority to regulate the practice of medicine; physicians may use legally marketed drugs or devices in any way that they believe, in their professional judgment, will best serve their patients"); *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 350; 121 S. Ct. 1012 1018; 148 L. Ed. 2d 854, 862; (2001) ("Thus, the FDA is charged with the difficult task of regulating the marketing and distribution of medical devices [and drugs] without intruding upon decisions statutorily committed to the discretion of health care professionals").

[18] *Warning Letter,* p. 2.

Gynecologists states that the REMS are outdated and substantially limit access to this safe, effective medication and advice the removal of the REMS.[19] The Mifeprex REMS unduly burdens women by:

> requiring healthcare providers who prescribe Mifeprex to be certified in Mifeprex REMS program; ensuring that Mifeprex is only dispensed in certain healthcare settings by or under the supervision of a certified prescriber; and informing patients about the risk of serious complications with Mifeprex[, and c]onsistent with the REMS, Mifeprex is not sold through retail pharmacies or over the internet.[20]

As a direct result of the FDA's decision to place Mifeprex in the highly restrictive REMS program with significant "Elements to Assure Safe Use," many women -- especially poor women living hundreds of miles away from the nearest "certified prescriber" -- are turning to Dr. Gomperts and Aid Access for reproductive health care. Dr. Gomperts is helping women in the U.S. exercise their constitutional right to terminate their pregnancies because the FDA has made it impossible for those women to safely terminate their pregnancies before viability in their local communities.

In *McCormack v. Herzog*, the Court of Appeals for the Ninth Circuit held certain Idaho statutes making it a felony for a woman to have an unlawful abortion and/or a doctor to perform an unlawful abortion to be unconstitutional.[21] Jennie McCormack was charged under the statutes after she miscarried shortly after taking medication she had obtained over the internet. The Court held that the doctor, Richard Hearn, had third party standing to assert the constitutional claims of pregnant women in Idaho based upon his claim that he could perform medical abortion using medication obtained by women directly over the internet. The District Court held that the Idaho statutes under which McCormack was charged with having an unlawful abortion using medication obtained over the internet and the statutes which Dr. Hearn could be charged if he ever performed medical abortions using medicines the women obtained over the internet were all unconstitutional and the Ninth Circuit affirmed.

The District Court summarized the law upholding a woman's right to choose as set forth in *Roe v. Wade*, 410 U.S. 113, 128, 93 S. Ct. 705, 35 L. Ed. 2d 147 (1973)) and *Planned Parenthood of Se. Pa. v. Casey*, 505 U.S. 833, 112 S. Ct. 2791, 120 L. Ed. 2d 674 (1992).

> In *Roe*, the Supreme Court held that a pregnant woman has a constitutional right, under the *Due Process Clause of the Fourteenth Amendment*, to choose to terminate her pregnancy before viability. 410 U.S. at 152-66. In *Casey*, the Supreme Court upheld *Roe's* "essential holding" by reaffirming "the right of the woman to choose to have an abortion before viability and to obtain it without undue interference from the State." 505 U.S. at 846. The Court in *Casey* also clarified that the right to obtain an abortion is not absolute and that state interests in maternal health and protecting fetal life can, in some circumstances, justify regulations of abortion. *Id.* at 846. *Casey*, however, jettisoned *Roe's* trimester framework of analysis for determining the validity of an abortion regulation and replaced it with an undue burden standard.
>
> In *Casey*, the Court asked whether a law designed to further the State's interest in fetal life, but which imposed an undue burden on the woman's decision before fetal viability, could be constitutional. *Id.* at 877. It answered this question "no." *Id.* The plurality opinion contained a summary of its salient points, which is useful for the issues presented here:

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[19] https://www.acog.org/Clinical-Guidance-and-Publications/Position-Statements/Improving-Access-to-Mifepristone

[20] *Warning Letter*, p. 2.

[21] *McCormack v. Herzog*, 788 F.3d 1017 (9th Cir. 2015).

> **• An undue burden exists, and therefore a provision of law is invalid, if its purpose or effect is to place a substantial obstacle in the path of a woman seeking an abortion before the fetus obtains viability.**
>
> . . .
>
> *Id.* at 878-79 (*citation omitted*).[22]

Aid Access is helping women who cannot afford to obtain an abortion in a clinic in the U.S. or have no access to doctors in the U.S. willing or able to prescribe misoprostol and mifepristone to their pregnant patients. If these women in the U.S. are prevented from using Aid Access, these women will either:

- try to end their pregnancy using a dangerous method, such as the use of caustic substances orally or vaginally or the insertion of sticks into the uterus, employed clandestinely to terminate an advanced pregnancy with a high mortality,[23] or
- be forced to continue their pregnancies and give birth in violation of their constitutional rights.

Being denied a wanted abortion has severe effects on women's health and wellbeing. Women who are forced to carry an unwanted pregnancy to term have four times greater odds of living below the Federal Poverty Level. In addition, women denied abortion are more likely to experience serious complications at the end of pregnancy including eclampsia and death; more likely to stay tethered to abusive partners; more likely to suffer anxiety after being denied abortion; and have a 25 times higher risk for significant maternal morbidity.[24] [25] [26]

Women in the U.S. have a 60-fold higher risk of dying from childbirth than from a medical abortion. The maternal mortality ratio for the U.S. is an estimated 26.4 maternal deaths per 100,000 births. This means 1 woman per 3,788 women dies from giving birth in the U.S.[27] A medical abortion is extremely safe with 1 reported death as a result of an undiagnosed extra-uterine pregnancy in 234,000 women in the U.S.

The FDA's attempt to deter Dr. Gomperts from prescribing misoprostol and mifepristone to U.S. women places a substantial obstacle in the path of all such women seeking an abortion of a nonviable fetus in the U.S.

CONCLUSION

Because of the REMS program, Dr. Gomperts' patients are unable to exercise their constitutional right to terminate their pregnancies in the local communities where they reside. Until the REMS restrictions imposed by the FDA on access to misoprostol and mifepristone are lifted, women seeking to

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[22] *McCormack v. Hiedeman*, 900 F. Supp. 2d 1128, 1143-1144 (D. Idaho 2013) (*aff'd*) (*emphasis added*).
[23] https://www.who.int/bulletin/volumes/92/3/14-136333/en/
[24] https://www.cdc.gov/reproductivehealth/maternalinfanthealth/severematernalmorbidity.html
[25] https://www.ansirh.org/research/turnaway-study
[26] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3711556/
[27] https://www.who.int/bulletin/volumes/93/3/14-148627.pdf

terminate their pre-viable pregnancies in the U.S. will be forced to exercise their constitutional right to choose by way of the internet. When U.S. women seeking to terminate their pregnancies consult Dr Gomperts, she will not turn them away.

Cordially,

Richard A. Hearn
HEARN LAW, PL

EXHIBIT A

- Not only can I not afford this but the circumstance is the worst. It was assault, I'm homeless and tryibg to get off the street. This is going to ruin anything I have spent the last year trying to get together and it is not much at thar I can't afford to get set back anymore. I can't do this and I don't want to. There is nothing I want less than to be pregnant right now. I am so upset this is happened to me and I want it to be over ASAP so please help me.
- A little more about my situation, I'm in a republican state that doesn't want anything to do with abortions. I have Medicaid insurance because I'm disabled with severe arthritis at a 22 and it's extremely hard to work. I currently live with my grandmother in government assistance because I escaped the abusive relationship I was in for 2 years. I found your site after doing a lot of research and I'm hoping you guys can help.
- I have Chronic lyme. Carrying a pregnancy would be too much for my body. I have 2 children already.. I work full time and still struggling to make ends meet.
- I have 3 disabled children already. I cannot financially or emotionally support one more child. The 3 I have already require so much and I have no help at all.
- I was raped by my daughter's father dad..I cannot have this u wanted baby..I just wanna put the rape behind me...
- When delivering my son 3 yrs ago I was told my the Dr that I should never have another baby due to the complications I had during my pregnancy, labor, and delivery. We were both lucky to have survived then.
- Thank you for your service. I tried to go to a local planned parenthood but my boyfriend tracked my location and showed up at the clinic to take me home. I can not have a baby at this time and I need to please find a way to safely end this pregnancy.
- I'm about six weeks pregnant and I cannot wait much longer. I don't know what 80 euros is but I don't even have $80, and I can't get to local clinics here. I live in a rural part of Virginia, US and have transportation issues. I'm already a single mom to an eight year old daughter. I've been dating the father of this baby for a very short amount of time. I really don't know him well enough to have a child with him, and I don't really know how he will react. I work full time but I don't qualify for any assistance and I can barely make ends meet as it is. I'm sure of my decision. I would appreciate any help or leads to any resources that you can offer. I would like to act quickly. Thank you for your time.
- Hello I am 4 weeks pregent was in a really bad abusive relationship I don't have much money I got health problems I cannot handle this pregency I need a adorable way..for the pill any help plz ty
- I am unable to receive aid from any of the organizations you have listed. I am asking for your help from the bottom of my heart, as you truly are my only option and only hope. I can make the donation, I will be more than willining but I can only make it when I get paid on the first of June. I will be more than happy to write a post dated check and send
- I have an appointment at my ob tomorrow to get my rogam shot. I wish I had $1000 to donate to this organization. My outlook, views and way of thing will forever be altered because of this. It makes me sad that women face such adversity when speaking out on abortion. Anyway, I just wanted to thank you all one last time. not for the medication that

I never could have afforded, but for the opportunity to continue providing for my 2 wonderful kids. Thank you. I love you all!"

- I cannot think of anything that would have made this a better experience. The staff that kept in contact with me were more than accommodating and made the entire process very comfortable and less stressful than any other means available to me. I will absolutely advocate for and recommend this program to others in need. Keep up the good work!
- Thank you so much, I really appreciate this. It brings tears to my eyes to know that y'all really are here to help people that are in desperate need. I will not forget about you guys when I find a job and able to send something. Thank you again ☺
- Because of you guys I can continue to focus on my education, and become a mother when ready for it. Thank you immensely for what you do.
  I hope to be able to give more to your organization as my income improves. You guys have been life-changers.
- Thank you for all your organization does. It is a difficult time in the US right now for women's healthcare and too many organizations say because abortion is legal in the US they cannot provide aid- it may be technically legal but clinics are states away and access is extremely limited.
- Thank you so much for your services, you have no idea how much this means to women world-wide.
- Once again, thank you so much for your help in the time I felt lowest and hopeless and your organization just saved me and reply every single spam mails from me....I appreciate it too much. From the bottom of my heart, thank you so much. Your organization help so many women and God bless you all.Thank you and best regards,
- I just wanted to reach out to you guys once again and thank you for the services you provide for women who are unable to use other services available to them, or who do not have access to other services at all. I'm not sure what I would have done if not for your wonderful program dedicated to women.
- I want to thank you, from the bottom of my heart, i wish i had enough words to explain how mamy ways you have helped me and my daughter have a chance at life and the ability to fight through all that is right now . Is the address you gave me ok to send a card? So many people that do good and help others, are to often left un appriciated and unreconised , the impact you have made on me amongst many others will always be remembered. Some of us are physically left with no other "right " options to save our lives and people like you help people like me feel making and taking the step is ok, while not feeling judged or frowned upon. Im forever greatful and god bless you.
- I cannot express my extreme gratitude for the help I am receiving from y'all. I have a job interview today and am so grateful that I will be able to move forward showing my full potential because y'all gave me the tools to do so. I will be able to take care of the family I have now. Thankyou so much for everything yall do!
- Thank you so much for everything. I have been really freaking out. Up until I started researching the abortion pill. Now there is hope. I had to have my last child because I could not afford abortion. I was in jail the last 6 months of that pregnancy, in maximum security. only being released 2 hours before my c section. This is where I sat in jail another year waiting for a bed at the state run drug rehab. Pregnant women, especially if they are an addict are thrown in jail all the time. It's so scary because all the people I would have thought to help me, did the opposite.

- Thank you Aidaccess for all your help. Becasue of you my 3 children will live a happier more fulfilling life. I will never forget this foundation and I will always recommend your services to others in my situation.
- Everything went fine. Thank you so much for all of your help. You guys literally saved my life. I have heart failure and would not be able to go through a child birth. Thanks again
- Thank you so much. You saved a very young couple from years of economic depression. And a challenging life. Thank you so much 🙏This file attached is us. We're a highschool couple. We both live in economically challenged families. Its tough to eat sometimes. Thank you so much.
- I also can't thank you enough and the organization for all that it has done for me and all the thousands of women that have utilized your services. I'm in tears typing this as access is a misconception in the US to services and services are not always client friendly. Women constantly have to deal with protesters or being handled in a rough manner by doctors and staff members, further shaming her, for her choice. I'm beyond thankful for AidAccess and similar organizations for all that it does for my sisters across the globe.
- I am very appreciative of the option that y'all have available. When i contacted Aid Access i was terrified, scared & had no idea what to do. So since then i have managed to put my big girl panties on. My fiance & i are very excited & have decided to pass on using the pills. Once again i want to stress how important & helpful y'all are to women who are in these situations& dont know where to turn. Have a blessed day. & thank you so much.
- And thank you guys sooooo much for providing this service. I have discreetly told my friends in need of it but not publicly. There is no better feeling than having access to this at home without having to leave and feel judged or beaten down by protesters, but in the comfort of your own home.
- I did in fact receive my package Thursday afternoon and have just had a successful abortion this morning. I appear to be doing just fine with no complications. I really want to thank you all for making abortion accessible for women around the world. I appreciate ya'lls help so much! Thank you again.
- I can not thank y'all enough on the service I have received from y'all. The MD is providing services that honestly are ground breaking but also long awaited. Waiting for the package was the most stressful thing. Thank you again, Jenni
- I just want to say thank you for this program...and thank for for believing I should have a choice in what happens with my body. If I am ever in a situation where I can donate, or recommend an organization to donate to...I will always have you in mind.
- THANK YOU THANK YOU THANK YOU THANK YOU THANK YOU THANK YOU THANK YOU!!!!!!!!!!!!!!!!!!!!!!!!

  I am so pleased with this service you are doing such a good thing helping women it is obsured how much they want to charge for medication that can simply be taken at home!!! Thank you for all the in depth information and for risking yourself for this cause you have no idea how much you are helping me!
- I'm just really super grateful that there are people out there that care enough to provide such a service for women who need it. It should be a very basic service that the government provides, but somehow it's not. I wish that the information was given at all

gynecologist offices, Planned Parenthood, Women's clinics, and so on. This information should not be so taboo because you never know unless it happens to you.

- Everything went well. I am so thankful for this organization for helping me in one of the worst times of my life. If it wasn't for Aid Access I would have had to drive two hours and pay $800 for the surgical procedure which I can not afford. Thank you again. I will highly recommend your services to those in my position.
- The experience went smoothly. I cannot express the deep gratitude I have for you guys. I don't know what would have happened if this was not an option available to me. Nothing could have been as gentle on my mental health as being able to do this on my own terms, in my own home, at a time I chose, without being poked or prodded or judged. Thank you.
- What you are doing for women is amazing. It was worry some putting faith in this process. I am mind blown that it wasn't a scam. Thank you so much.
- Honestly, this service was a life saver. Your team was very responsive and incredibly helpful. They were very willing to work with me and I owe them so much.
- I honestly cannot believe how easy you made this whole process. I was so nervous and worried. I could not afford to go to a clinic, and was afraid that after having an ultrasound and the counseling session they make you go through, that I would be conflicted. Being able to do this from home and having you all on standby with such quick responses made it so wonderful for me. Yes this is never an ideal situation for anybody, but this happens in life. I am so eternally grateful for your services and helping me to get through this.
- I will email tomorrow night to let you know how much money I was able to collect. Thank you for giving so many women home. You guys are angels!
- I feel so much better physically & emotionally, again I can't thank you enough I don't know how I would have done this without your organization. Thank you!!!
- The aid access team is awesome. Felt like they held my hand throughout the process🙏
- I don't know what I would have done without Aid Access, they saved my future and my life.
- I do not need your services anymore but I did want to respond to let you know how very much I thank you and I am grateful to know that there is an organization such as yours available to help women in need. at a time when i truly wasn't sure what to do, I found your page.
- I am crying tears of joy. Thank you for the work you do, giving me my own choice on how to live my life without fear of dealing with the stigma going to a clinic brings and making it financially possible. There are no words to express my deep gratitude for this service. You changed mine, and countless other I'm sure, life for the better.
- If this is the best decision for you dont feel bad about it. Aid Access is real and the pills are safe and work. I went to the Er because i was scared of complications and had some cramping from the placenta trying to pass and later it did. I dont regret my decision and I thank Aid Access for all your help!
- I want to say thank you again for helping me and all of the women who receive your loving and compassionate assistance. You make the world a better place. I am grateful for your work and would love to be a part of your work somehow... thank you thank you
- I just want to say thank you for the help. I am from the .... Indian Reservation in South Dakota USA. Its one of the poorest places in the USA. I was able to afford this pill and

not have to travel 5-9 hours to have an actual procedure done which makes it even less affordable when you factor in travel.

- I am deeply grateful for this help. I wish it were more readily available through regular doctors here without resistance or shame. Thank you.
- Hi this is .....mom. Everything went well. I did have her examined in the ER tonight and they prescribed Keflex for a UTI but said that she looks fine. We were able to say she had a miscarriage with no problem and they were able to confirm the pregnancy has ended. We are relieved. Thank you so much for helping, I dont know what she/we would have done without your assistance.
- Package arrived and medicines were taken over the past two days. Everything went as outlined and i cannot thank you enough for making this as streamlined an experience as possible. I hope more people take comfort in knowing that this service is available to those who struggle to find access or are in the position where they need things to be as discreet as possible. Women should be in control of what happens with their own bodies and do not need anyone to talk them out of the tough decision they are making on their own or tell them that what they are doing is wrong. Again thank you so very much!
- I'm just writing to let you know all is well. I want to thank you again for the work you are doing to help women worldwide. I could have never afforded these medicines had I tried to buy them through a healthcare provider here in the United States, and for that I am eternally grateful to your organization. Please continue your efforts, as you have not only helped save my life but I'm sure you have impacted countless others. I'm happy to report I experienced no ill side effects to the medicines, and I am feeling well after everything is done. I followed your instructions thoroughly and everything went as expected. Once again, thank you for your help, and Happy Holidays to you all.
- Thank you for your drive for reproductive equality because it has made the difference in my life and my future. Please stand strong against the FDA! You do work that has directly made a measurable and specific effect on my life for the better. For that, I am eternally grateful.
- Thank you for your help and aide during this horrible time. Thank you for helping women in need.
- Thank you so much for your help. I was feeling so hopeless and trapped. I can't express how much this means to me. You are an amazing organization, and I will be forever grateful for your help.
- I just want to say thank you for guiding me through the entire process, and following up with me whenever I needed any help. You have no idea how much you've helped me not just for this process but in the future. I can never thank you enough. Thank you.
- I was extremely scared it wasn't going to work, and that idea frightened me so much because I have a very religious family who would probably shun me if they found out what happened. I also live in the Bible Belt where the topic of abortion has been discussed heavily in the past month which put me even more on edge about the entire situation. I just can't describe the fear that gripped me, the sadness I felt about having to go through this situation, and the immense pain I felt after taking the pills. Even though I've always wanted children, making this decision was easy. I was under the impression that there wasn't any chance I was pregnant, so when I missed my period, I was confused at first then that turned to panic. The father had taken off the condom without informing me, and purposefully tried to get me pregnant. It was a cruel situation to put me in. I had

to lie to him about starting my period. This situation was traumatizing to say the least, and I'm not having sex again until I get the birth control arm implant. I don't want to experience anything like this ever again, but I am so thankful that Aid Access made this process easier for me. There's no way I could have gotten to the local clinic. Abortions are only available on a few days a week, and they're always at times I work. I also don't drive, so discreetly visiting the clinic wasn't an option. There are also regular protests outside the clinic. I'm also waiting to hear back from graduate schools right now, and having a baby would make starting in the fall impossible. I know this was the best decision for me, and I thank you from the bottom of my heart for making this so affordable as well. The clinic I referred to would have charged me $700 for the pills, and that was an unrealistic number for me. Finding this website was a miracle for me.

- I just want to say thank you for guiding me through the entire process, and following up with me whenever I needed any help. You have no idea how much you've helped me not just for this process but in the future. I can never thank you enough. Thank you.
- I decided to continue the pregnancy, but it took a lot of weighing the options to get there and I'm certainly happy that I actually had a choice given the current rhetoric in the US surrounding abortion. Please keep providing this for women. It is really important. I felt so relieved when the package arrived even though I did not use it.
- I recommend this. It helped me when I was in a low place. Debating ending my own life bc I couldn't possibly have another child. Yes. This is deep but if it wasn't for this.. I would of had no solutions. My state has so many regulations or wants way to much money. I'm very grateful for this service. You helped me more then you'll ever know.
- I am so thankful for this service. It cost 1/5 of what a surgical procedure would have cost. Also I never had to talk to anyone about it or ever leave my house. The actual procedure was just like having a normal period. I was about 5.5 weeks along at the time of using this medical method. I wish I could express how thankful I am for the people that make this possible. I wish I could give them a big hug and tell them how much I appreciate theis and they helped me in a time that could have been a major catastrophe.
- Aid access has literally saved me. I'm so sad for all the girls in the US who can no longer access this service when they are in need now that the US blocked AidAccess
- Please work hard to become available once again in the states. You helped me so much, I know this organization is needed by others like me.
- Yes I do and thank you very much without you I would have brought a child into the world that hadn't deserved to be raised with nothing I an currently homeless and bounce from friends homes and couldn't imagine having a child with me. Me and my husband had an accident and sometimes it happens but we talked and I niether of blus feel poorly if our decision and felt it was for the best and that we will plan our next and taking the right steps towards not concieving until then you guys were a blessing and you helped me when I only had enough to pay for half and this help will stay between us if I have any friends in need of f this help I will surely send them to your website all the pain was worth the choice to have a kid when we can better it's life not worsen it thank you very much.
- This experience was better for me because of the situation I was in I lost everything my job and my house etc I lost hope of caring for another child I worried about my health also had a boyfriend that verbally abuse me. I am thankful that I was able to receive the help that I needed

- The more I thought about it, I decided to continue the pregnancy and keep the baby. But I think this service is absolutely amazing and would recommend to friends in need of help.
- Thank you again for assisting in this manner. It was much more convenient than attending a clinic appointment and obviously having to pay their desired prices. Seems a bit out of range for them to simply provide the same treatment. The same pill at a clinic in Pennsylvania , America (usa) ranges between 400-550 US dollars . So it was nice to have this available to people at a much cheaper , more descrete process. It just goes to show how corporate America has their hands in the medical field leaving no alternative . Im sure plenty more women would prefer to recieve your services , though Im certian many dont even know your existance . Im not sure how ,if possible, you would be able to inform more of these ladies , but if there is a legal way I would definately suggest getting the word out there. I intend for this to be the first and last i ever shoudl need to take these measures, but I can say I greatly appreciate that you were available and willing to help .
- I want to Thank everyone involved in making this choice possible for me and guiding me through the steps, now I have to pass it forward and inform many other women who may be in need of assistance. May all the paths be cleared for this organization and again Thankyou so very much for the help
- I just want you to know how much it meant to me to have this option. I have a lot of kids and the youngest, has had open heart surgery and I didn't go home for over a month so I could be with him 24/7 during his hospitalizations. My husband couldn't work because he needed to care for our other children. I am so, so thankful that this was an option. I truly thank you from the bottom of my heart for what you do.
- I honestly cannot believe how easy you made this whole process. I was so nervous and worried. I could not afford to go to a clinic, and was afraid that after having an ultrasound and the counseling session they make you go through, that I would be conflicted. Being able to do this from home and having you all on standby with such quick responses made it so wonderful for me. Yes this is never an ideal situation for anybody, but this happens in life. I am so eternally grateful for your services and helping me to get through this.
- Thank you for all you do for us. I would have been charged 500 USD at an abortion clinic which is completely out of my rage.
- I felt like I had to go through a great length of unnecessary struggle and stress to get the care that I desperately needed. After I found Aidaccess a lot of that stress subsided. Thank you
- You were all very supportive, informative, and helpful. If it wasn't for you, I'd be stuck in an unsafe relationship not only for myself, but for my toddler daughter. Thankfully, he left us after finding out about the "miscarriage". Thank you for all you do. Ironically, you are saving and changing lives with this service.
- Thank you for bein brave and existing helping women and encouraging to speak up and out about our bodies. It's our right to make decision based upon our existence and our health including mental health. Not everyone is ready to go through an entire pregnancy. Let alone raise a child afterwards.
- I am very great full for this service, being on a limited income made it hard to be able to afford a clinic. I was glad I did not have to pursue other methods
- thank you for potentially saving my life

- This helped me tremendously, I was extremely scared to go to a clinic where so many people know my family and myself in a small town and also I was having extreme financial problems, so this helped me more than anything. I would not have been able to afford the 500$ abortion cost that it would have took and I'm not sure what I would have done.
- I am so thankful for this service. I could not afford $600 for an abortion, and am not able to take care of another child at this time in my life. Thank you
- I was very satisfied. It's nice that a site like this exists to help women when help is not always easily accessible these days. I feel confident that I will not ever need this service in the future but I would definitely recommend it to anyone in a similar situation.
- You are helping women. Please continue your services as long as possible. This is a miracle to the women who need it.
- The support was there every step of the way. I would always receive an follow up email from your team which greatly comforted me. I could actually afford the pills and was able to do it in the privacy of my own home. I'm so greatful for your services and will always support this organization.
- Before this experience, I have not agreed to the abortion. But, now I realized that the decision of abortion must be under women right. Indeed, it is important for the quality of life of women and fetus It will be beneficial to women right if we do conceive it and request for women abortion right, I have learned throughout this experience.
- Great website experience. I hope more women find it. I was hesitant that it was a legit site and I wasn't going to get scammed. Pain measure should be exaggerated, tell women that contractions will be intense and extremely painful, feeling more like labor than period. Hot compress for the belly reduces some of the discomfort. Tell women that the abortion/miscarriage starts almost immediately after taking the pills. Advertise this website, to get help out there for women before is too late.
- Thank you. I was able to follow the directions the day the package arrived and successfully terminated on March 15th. I've since had a follow up with my GP and generally have felt so much better in terms of my mental health, fatigue, and nausea.
- I live in Georgia which passed a 6 week abortion ban in the House & Senate the week after I was able to get help through AidAccess. Thank you so much for the work that you do.
- Thank you so much for what you do and I know that, recovering from back surgery, if I had carried the pregnancy all the way through my back would not have healed properly and damage would have been done.
- Overall everything turned out alright. I hope I will not have to go through this again, but this method was much more financially stable and fluid than the other options available to me. There is only one clinic in my state that caters to this need; it's pricey, distant, and the scheduling is on their terms. Overall I was satisfied. Thank you for making this service available to women.
- This service helped me to get rid of an abusive relationship and to help me continue with my life. I'm forever in debt to you all and I appreciate you so much.

- Thank you so much to aid access for everything you do for women and promoting a woman's right to handling these situations at home in privacy.
- Despite the circumstances everything went well & it literally saved my life . I will most definitely recommend this site to anyone of my friends or anyone going through.
- This was a great experience and would recommend to someone who feels they can handle this at home. The abortion clinic wanted to charge me 400 with out this service I could not have afforded the pill. I think what you are doing is amazing.
- I am truly grateful for the access to care that you are providing. Thank you.
- Aid access is a needed service to women in the us
- I'm very grateful and impressed with how everything went and thank you all so so so much for allowing me to keep control over my own body and my own decisions ♡♡♡
- You all prepared me, answered my questions so quickly, I will always be grateful for you. Between heart issues and the pregnancy hormones setting off my depression again to the point I wanted to die you guys saved my life. My husband and I plan to donate in the future.
- This experience was amazing. Dr Gomperts and her organization are providing access to women who would otherwise turn to dangerous alternatives to ending their pregnancy. I am grateful for her. I have no complaints about the process.
- Just wish I did not have to go through this but thank you for help. I'm glad there is something like this to help people like us.
- Wonderful organization with great info and feedback.
- The service I received was awesome, helpful and understanding I am so so grateful this existed because I live in an area where the nearest clinic is over an hour away and you're required a minimum of 2 visits before allowing for pills, I don't have the time with work to take all these days off and explaining this to my place of work would be even more frustrating and complicated this device should be available to all women!!
- This was a great experience and would recommend to someone who feels they can handle this at home. The abortion clinic wanted to charge me 400 with out this service I could not have afforded the pill. I think what you are doing is amazing.
- It was the best experience I could have had under the circumstances
- I was hesitant on wheather or not I wanted the abortion and sometimes but I knew I had to and at the end of the day I knew that's what was best for me. Now a month after the abortion I'm happy and healthy, 'my boyfriend is going to the army and we are both happy with our decision. This is an amazing company and I know without it I most likely would have kept it, I'll forever be thankful
- this was the best experience it could be given the situation ... thank you for being there :)

- I was very happy such a service is offered. There was no way i could have afforded this at the clinics that provide this service, nor could i afford another child at this time in my life. Thank you!
- I am just very grateful this was an option. And I'm very sorry for all the people who can't be helped now because my country has made you stop shipment.
- All the support from the aid access made total difference,the emails to check on me,the fact that if I didn't have enough money to get the pills they would donate to me,the instructions were very clear.Even though the circumstances were not good they made it easier and were extremely helpful.I am happy with my experience.
- I think you guys are amazing for providing this service to women who are not in a position to go to a clinic or are in an abusive relationship.
- The delivery came fast than expected, which was very pleasing. The direction were very easy to follow and everything that happened had been previously described/explained. I definitely preferred doing this at home due to having gone to a clinic before ordering and being denied care. Being at my own home without anyone trying to pressure me by "educating" me on the abortion was much more peaceful and gave me a better sense of control and less guilt.
- I'm so grateful that you guys exist I never would have been able to afford the 900$ the clinic told me I needed.
- Thank you for your help during such an uncertain and stressful time
- I was so relieved I could escape a very complicated situation with your help and am so grateful. Thank you!
- But Aid Access is incredible. Who knows what kind of lasting psychological damage and shame I would have experienced during a Planned Parenthood experience had I not found Aid Access. I'm still unsure if getting an abortion is morally right but I am so grateful Aid Access exists. It was going to cost $750 plus a 4 hour drive to another state to go to Planned Parenthood and would have forced me to go through additional weeks of pregnancy because appointments were so booked out. I may have actually worried about all the options above at some point but my experience and just grateful-ness for Aid Access completely outweighed those worries. I can't thank you enough that you would selflessly take up this fight. Thank you so much.
- It was perfect! Saved my life.
- people may be skeptical but i am 30 from the US with 2 kids and this was just what i needed. i want to thank you for providing this service. this abortion was a completely person situation and your service was descreet and i appreciate that so much.
- Before accessing this service, I had performed an abortion myself at home by using large gauge crotchet hooks to dilate my cervix a bit and then attaching plastic tubing to a syringe and suctioning the fetal/pregnancy tissue. I was very nervous to do this and although I successfully ended the pregnancy, I also got a small tear on my cervix that would not stop bleeding. I was able to see a doctor and they cauterized the spot and it was

fine, but the entire process was dangerous and stressful. I am educated and upper-middle class. I could not travel for an abortion because I am the primary caregiver of a special-needs child. Having this service available allowed me to terminate my pregnancy safely, effectively, and with discretion.

- Thank you so much for this service you provide to women. Having these pills arrive to my home where I could do this in the safety/security of my own home without embarrassment or judgment from others was so huge for me. Thank you for making these pills affordable. Having these same pills at planned Parenthood would cost around $600! Your emails and instructions were clear and I understood how to use them. Thank you SO much for providing this service. Please don't stop, and continue to help women
- You were very supportive and I am thankful that you were there.
- You guys are helping soo many females out here that wants to get abortion but don't have that much money to go to the hospital.
- This was the best option for my family and I
- It was perfect. I appreciate you guys so much.
- Nothing could have made this service better. I received the pills before expected and I had enough information on how to use them properly. If anyone I know is ever in my situation, I will be directing them to Aids Access.
- I'm very grateful that I was able to get the pills. I know I made the right choice for me. I hope that AidAccess is able to keep providing this service to women all over the world.
- Being able to handle the situation privately was the most important thing but was also appreciative of the support aidaccess provided.
- I appreciate the service i got and was well informed on what to do. This saved me a lot of money and time and I will forever be grateful!
- This service was very helpful and informative. I can't think of anything that could be done to improve. The communication was effective and everything went accordingly.
- You are giving a great support to people that are in needs. Keep up the good work.
- I am very grateful that I was able to use this service. I hope you continue to help women around the world. Thank you!
- This is a great service and support. Thank you so much.
- I'm am grateful for the service y'all provide. Affordable and private. It was so much easier than facing clinic protesters and long waits. It was as close to a natural loss a possible. The hardest part was the anticipation of waiting on mail to arrive. It was not an easy thing to do but what was best for my life at this time. Thank you for your services.
- It would have been better if there were more options for women in the United States to choose without having to visit a provider, which may be hours away, and to also avoid the feeling of being judged. I am thankful for the help.
- I am extremely appreciative of your services. I honestly, was ready to end my life because of this. Thank you.
- I'm very greatful and everything went better than expected. Danke

- If it wasn't for aid access I wouldn't know what to do, so I thank you for your help
- Very much appreciate that there are services that make it more accessible, safe and comfortable for women to take control and make decisions for themselves.
- The process was phenomenal, given the circumstances, in that I was given so much information, follow up, and genuine care from all the communications I received. I didn't feel alone, I didn't feel shamed, and I felt empowered to make the right choice for me in a way that was personal, private, and affordable. The only thing I had to look up outside of the information I was provided was what I should expect to physically see as the process went on, and a little more info about how long after taking each pill I should start feeling symptoms. I would become worried they weren't working properly, or that it wasn't working quickly enough and wouldn't be a complete abortion, things like that. Now, most of that could be due to the fact that it's a highly emotional situation, there are hormones going crazy, and things like that, but the more information I had the more relaxed I felt. Thank you so much for supporting and empowering women. I just really appreciate the work you guys are doing for women, especially those who can't afford traditional or government-provided aid.
- Best decision and Im blessed to have come across this help from aid access. I will forever be in debt to your services. You helped save my life as well as getting my other kids on track
- Thank you for everything and the service you provide for women that have difficult times.
- All went well, glad you are able to help people in need.
- I was happy to have found a program who supports women in this kind of situation and willungbto help financially.
- I was treated with so much compassion and understand it was very heartwarming
- I appreciate this being accessible, instead of having to go in and make an appointment. The privacy made this such a better experience.
- I think was a good experience to have in the privacy of my own home. Always do it sooner rather than later to try to lessen the chance of complications.
- You all have made this as easy and painful less as possibly possible. I'm not religious but God bless all of you. Thank you so much
- Please continue to help women like me. Thank you!
- I did not have any other options besides this. Aid access really helped and didn't make me justify myself.
- Thank you so much for helping me out of an unwanted pregnancy. A weight has been lifted off my shoulders
- I was very pleased to see (multiple times) that financial hardship was not a barrier of obtaining medication. Offering help to those who need it, regardless of profit, is an honorable cause.

EXHIBIT D

IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF WISCONSIN

UNITED STATES OF AMERICA

v.

URSULA WING,

Defendant.

INDICTMENT

Case No. 19 CR 84 JDP

18 U.S.C. § 371
21 U.S.C. § 331(a)
21 U.S.C. § 333(a)(2)
21 U.S.C. § 334(d)(3)
21 U.S.C. § 853 (p)
28 U.S.C. § 2461(c)

THE GRAND JURY CHARGES:

COUNT 1

Factual Background

1. At times material to this indictment:

a. Defendant URSULA WING was a resident of New York City, New York. WING operated a blog under the name "the Macrobiotic Stoner," and ran it from her home in New York City. WING also operated a fake jewelry business under the name Morocco International Inc., which she used to process the payments received from clients of the Macrobiotic Stoner.

b. Through these entities, WING sold prescription drugs to customers in the United States and around the world. These prescription drugs were foreign-sourced versions of mifepristone and misoprostol, which were not versions approved by the United States Food and Drug Administration (FDA) for use in the United States.

c. WING could not legally sell prescription drugs because she was not licensed to do so. WING did not possess a valid wholesale drug distribution license, a valid pharmacy license, or a license to prescribe prescription drugs in New York state, Wisconsin, or any other state. WING also was not duly registered under Section 510 of the Federal, Food, Drug, and Cosmetic Act (FDCA), as a drug manufacturer.

d. WING imported the foreign-sourced prescription drugs in wholesale quantities into the United States from India. WING broke down the bulk shipments, and repackaged them into retail quantities. WING then mailed the foreign-sourced versions of mifepristone and misoprostol to her clients by U.S. Mail. WING intended that the foreign-sourced versions of mifepristone and misoprostol be used by her clients to affect the structure and function of the human body.

e. WING used computers at her home to operate her business, and to communicate with her business clients via email, using two email addresses: macrobiotocstoner@gmail.com and moroccointernationalinc@gmail.com.

f. WING maintained a bank account for Morocco International Inc. at JPMorgan Chase Bank. WING used the PayPal online money transfer system to receive payments from her clients. WING deposited the business receipts from PayPal into her JPMorgan Chase business bank account. In March 2018, WING obtained a merchant account from Square, a credit card processing service, and began accepting credit cards as a source of payment. In June 2018, WING applied for a Western Union business account under the business name Morocco International Inc. On the application, WING

indicated she was in the business of selling jewelry, clothing and housewares imported primarily from Morocco and India, to online customers in the United States.

Legal Background

U.S. Food and Drug Administration – Drug Definitions

g. The United States Food and Drug Administration ("FDA") is the federal agency within the executive branch of the government responsible for protecting the health and safety of the American public by enforcing the Federal Food, Drug, and Cosmetic Act (FDCA). Among the purposes of the FDCA is to assure that drugs sold for human use are safe, effective, and bear accurate labeling containing all required information. The FDA's responsibilities under the FDCA include regulating the manufacture, labeling, and distribution of all drugs shipped or received in interstate commerce.

h. Under the FDCA, "drugs" are defined as, among other things, articles intended for use in the cure, mitigation, treatment or prevention of disease in humans (21 U.S.C. § 321(g)(l)(B)); articles intended to affect the structure or function of the body of humans (21 U.S.C. § 321(g)(l)(C)); or articles intended for use as components of other drugs (21 U.S.C. § 321(g)(1)(D)).

i. The term "label" is defined as a display of written, printed, or graphic matter upon the immediate container of any article. (21 U.S.C. § 32l(k)). The term "labeling" is defined as all labels and other printed or graphic matter upon any article or any of its containers or wrappers, or accompanying such article. (21 U.S.C. § 32l(m)).

j. "Prescription drugs" are defined under the FDCA as: (a) those drugs which, because of their toxicity or other potentiality for harmful effect, or the method of their use, or the collateral measures necessary to their use, are not safe for use except under the supervision of a practitioner licensed by law to administer such drug; and (b) those drugs limited by an FDA-approved application to use under the professional supervision of a licensed medical practitioner (21 U.S.C. §§ 353(b)(l)(A) and (B)).

k. A drug is "misbranded" if, among other things: (1) its labeling is false or misleading in any particular manner (21 U.S.C. § 352(a)); or (2) its labeling does not bear adequate directions for use (21 U.S.C. § 352 (f)(l)); or (3) it is an imitation of another drug (21 U.S.C. § 352(i)(2)), or (4) it is offered for sale under the name of another drug (21 U.S.C. § 352(i)(3)); or (5) the drug is a prescription drug dispensed without the valid prescription of a practitioner licensed by law to administer such drug (21 U.S.C. § 353(b)(l).

l. "Adequate directions for use" is further defined by regulation as "directions under which the layman can use a drug safely and for the purposes for which it is intended." (21 C.F.R. § 201.5). Because prescription drugs by definition can only be safely used under the supervision of a licensed medical practitioner, they have to qualify for an exemption to this labeling requirement to be legally distributed in interstate commerce. The exemption is set forth in Title 21, Code of Federal Regulations, Section 201.100, which states that a prescription drug is exempt from the requirement of Title 21, United States Code, Sections 352(f) (that its labeling contain

adequate directions for use) if the following conditions of the exemption are met, including: (1) that the drug be in the possession of persons regularly and lawfully engaged in the manufacture, transportation, storage, or wholesale distribution of prescription drugs; or (2) in the possession of a retail, hospital, or clinic pharmacy regularly and lawfully engaged in dispensing prescription drugs; or (3) in the possession of a practitioner licensed by law to administer or prescribe such drugs; and (4) the drug was to be dispensed pursuant to a valid prescription. In addition, if the drug was one required under the FDCA to have an approved application prior to distribution, the drug had to bear the FDA-approved labeling.

m. A prescription drug is dispensed only upon the written prescription of a practitioner licensed by law to administer such a drug, or upon an oral prescription of such practitioner, which is reduced promptly to writing and filed by the Pharmacist. The act of dispensing a drug contrary to these requirements results in that drug being misbranded while held for sale. (21 U.S.C. § 353(b)(1)).

n. The FDCA provides that before a "new drug" can be distributed in interstate commerce, its manufacturer must obtain FDA approval of a New Drug Application, an Abbreviated New Drug Application (for generic drugs), or an Investigational New Drug Application (for drugs being researched in humans). To receive approval to market a new drug, the manufacturer must submit information showing that the new drug is safe and effective for its intended use, or for generics to show bioequivalence to the pioneer (brand name) drug. (21 U.S.C. § 355).

o. Under the FDCA, the commission of the following actions constitute a "prohibited act" under the statute:

- The introduction or delivery for introduction into interstate commerce of a misbranded drug. (21 U.S.C. § 331(a));
- The receipt in interstate commerce of any drug that is misbranded and the delivery or proffered delivery thereof for pay or otherwise. (21 U.S.C. § 331(c)); and
- The doing of any act with respect to a drug while such article is held for sale after shipment in interstate commerce which results in the drug being misbranded. (21 U.S.C. § 331(k)).

The Drugs

p. Mifepristone (brand name Mifeprex) is a "drug" within the meaning of Title 21, United States Code, Section 321(g)(1), and a "prescription drug" within the meaning of Title 21, United States Code, Section 353(b)(l). Mifepristone is an FDA-approved drug, and when used together with another drug called Misoprostol, will medically terminate an early pregnancy (up to 70 days or less). Mifepristone is a prescription drug, but is not available to the public through pharmacies; its distribution is restricted to specially qualified, licensed physicians, and the administration of Mifepristone is subject to an FDA Risk and Evaluation Mitigation Strategy (REMS). Among the REMS requirements are that mifepristone may only be dispensed in clinics, medical offices, and hospitals by, or under the supervision of, a certified healthcare

provider, and the healthcare provider must obtain a signed Patient Agreement Form before dispensing mifepristone.

q. Misoprostol (brand name Cytotec) is a "drug" within the meaning of Title 21, United States Code, Section 321(g)(1), and a "prescription drug" within the meaning of Title 21, United States Code, Section 353(b)(l). Misoprostol is an FDA-approved prescription drug used to treat stomach ulcers. The FDA-approved labeling further states in bold lettering: "Cytotec should not be taken by pregnant women to reduce the risk of ulcers induced by nonsteroidal anti-inflammatory drugs (NSAIDs)."

U.S. Department of Homeland Security – Import and Export Regulations

r. The Department of Homeland Security, Customs and Border Protection (CBP) is the agency responsible for administering the laws governing the importation into the United States of merchandise, including drugs.
CBP is also responsible for the enforcement of applicable statues associated with the export of goods from the United States.

s. Federal law requires that, among other things, all merchandise brought into the United States by any individual: (1) be declared to a Customs Officer at the port of first arrival in the United States; (2) be declared on a conveyance en route to the United States on which a Customs officer was assigned for that purpose; or (3) be declared to a pre-clearance office in a foreign country where a United States Customs office was stationed for that purpose.

t. An importer of merchandise into the United States is liable for duties, taxes, and fees on the imported merchandise. The importer of record is

responsible for filing entry documents with the CBP, which classifies the imported merchandise, identifies its value, and provides any other information necessary to enable CBP to assess duties properly, collect accurate statistics, and determine whether other applicable legal requirements, if any, have been met.

u. Whenever drugs falling under the jurisdiction of the FDA are declared or offered from import into the United States, the CBP notifies the FDA to determine whether the drug should be sampled and whether importation of the drug was lawful under the FDCA.

U.S. Postal Service – Mailing Regulations

v. The United States Postal Inspection Service (USPIS) is the law enforcement arm of the U.S. Postal Service (USPS) whose duties include the enforcement of the laws that defend the nation's mail system from illegal or dangerous use, and ensure public trust in the mail.

w. When utilizing the United States Postal Service, an exporter of record is required to complete a United States Postal Service form number 2976 or 2976-A, and list among other items, a detailed description of the contents. The information provided on the form allows CBP to assess duties properly, collect accurate statistics, and determine whether other applicable legal requirements, if any, have been met.

Conspiracy

2. From in or about June 2016 and continuing to on or about June 21, 2018, in the Western District of Wisconsin and elsewhere, the defendant,

URSULA WING,

knowingly and intentionally conspired with other persons, known and unknown to the grand jury, to defraud the United States for the purpose of impeding, impairing, obstructing, and defeating the lawful government functions of the following federal agencies through deceit, craft, trickery and means that were dishonest, more specifically:

a. The U.S. Food and Drug Administration (FDA) in the administration and enforcement of the laws and regulations pertaining to the FDCA.

b. The U.S. Department of Homeland Security, Customs and Border Protection agency (CBP) in the administration and enforcement of the laws and regulations pertaining to the import and export of merchandise, including drugs, into and out of, the United States.

c. The U.S. Postal Inspection Service (USPIS) in the administration and enforcement of the laws pertaining to the use of the U.S. mails.

Manner and Means

The manner and means by which the conspiracy was sought to be accomplished included, among others, the following:

3. It was part of the conspiracy that WING illegally smuggled into the United States misbranded prescription drugs from India. WING obtained versions of misoprostol and mifepristone which, according to the packaging, were manufactured by Cipla Ltd in India. These foreign-source drugs were not approved by the FDA for distribution in the United States. This imported merchandise would contain a U.S.

Customs Declaration Form CN22 falsely stating: (1) the contents were "personal supply medication;" and (2) the contents did not contain any dangerous articles or articles prohibited by postal or customs regulations.

4. It was further part of the conspiracy that WING sold these misbranded prescription drugs to customers in the United States and around the world. Because WING was not licensed to prescribe or distribute prescription drugs, WING used a secret webpage called "My Secret Bodega," on her Macrobiotic Stoner blog at: www.macrobioticstoner.com/my-secret-bodega.com, to hide her activities from the FDA, CBP and USPIS. On this page, WING offered misoprostol and mifepristone, individually, in various quantities and prices. WING also offered misoprostol and mifepristone, together as a "MTP Kit," in various quantities and prices.

5. It was further part of the conspiracy that WING attempted to hide her activities from the FDA, CBP and USPIS by disguising the nature of her sales of the misbranded prescription drugs that were ordered on her secret webpage. First, WING created a fake company called "Fatima's Bead Basket" which she listed as the shipper on the envelope going to the customer. Second, WING inserted a necklace or other item of jewelry in the shipping envelope to serve as the cover piece of merchandise being mailed to the customer. Third, WING packaged the misbranded prescription drugs in a smaller packet that was in a hidden panel and taped to the inside of the shipping envelope. Fourth, WING disguised the nature of the item being purchased by listing on the invoice alternate jewelry product names, each of which had a code to indicate the actual item being ordered. These jewelry product names included: "Gold electroplate

twisted multi-rope collar necklace," which stood for a "MTP Kit of 1 mifepristone 200 mg pill and 4 misoprostol 200 mg pills."

6. It was further part of the conspiracy that WING mailed these misbranded prescription drugs from the United States to customers around the world, and falsely characterized the exports on the US Customs Forms as jewelry.

7. It was further part of the conspiracy that WING created a fake online jewelry business called Morocco International at www.morocointernational.com and a fake merchant processing portal at https://moroccointernational.com/checkout/ for use as a cover for selling the misbranded prescription drugs on her secret webpage. By creating this fake merchant processing portal, WING allowed her Macrobiotic Stoner clients to pay for the misbranded drugs using their credit cards, with the sales showing up on the merchant account as jewelry, and not mifepristone or misoprostol.

Overt Acts

In furtherance of the conspiracy, and to accomplish its objectives, the following overt acts were committed in the Western District of Wisconsin, and elsewhere:

8. On or about January 16, 2018, WING caused to be mailed within the United States, misbranded prescription drugs from New York City, New York to Crystal, Minnesota (USPS Tracking Number 9405809699937270383537);

9. On or about January 27, 2018, WING caused to be mailed within the United States, misbranded prescription drugs from New York City, New York to Portage, Wisconsin (USPS Tracking Number 9405809699938161709504);

10. On or about January 30, 2018, WING caused to be mailed within the United States, misbranded prescription drugs from New York City, New York to Wisconsin Rapids, Wisconsin (USPS Tracking Number 9405809699939660431873);

11. On or about June 8, 2018, WING caused to be imported into the United States, misbranded prescription drugs from New Delhi, India to New York City, New York (EMS Tracking Number ED877904579IN);

12. On or about June 15, 2018, WING caused to be imported into the United States, misbranded prescription drugs from New Delhi, India to New York City, New York (EMS Tracking Number ED877910163IN);

13. On or about June 15, 2018, WING caused to be imported into the United States, misbranded prescription drugs from New Delhi, India to New York City, New York (EMS Tracking Number ED877914386IN);

(All in violation of Title 18, United States Code, Section 371).

COUNT 2

1. Paragraph 1 of Count 1 is incorporated here.

2. From on or about January 29, 2018 to on or about February 2, 2018 in the Western District of Wisconsin, and elsewhere, the defendant,

URSULA WING,

with the intent to defraud and mislead, introduced, delivered for introduction, and caused the introduction and delivery for introduction into interstate commerce, from the State of New York to Wisconsin, prescription drugs, mifepristone and misoprostol, that were misbranded, more specifically: (1) they were dispensed without a valid

prescription from a practitioner licensed by law to administer such drugs (21 U.S.C. § 353(b)(1)); and (2) the labeling of the drugs lacked adequate directions for use by a lay person (21 U.S.C. § 352(f)(1)).

(All in violation of Title 21, United States Code, Sections 331(a) and 333(a)(2)).

FOREFEITURE ALLEGATION

1. Upon conviction on Count 1 or Count 2 of this indictment, the defendant URSULA WING, shall forfeit to the United States, pursuant to 21 U.S.C. § 334(d)(3) and 28 U.S.C. § 2461(c), all quantities of the misbranded drugs distributed by WING via the Macrobiotic Stoner website, as evidenced by her PayPal and Square deposits.

2. If any of the property described above, as a result of any act or omission of the defendant[s]:

a. cannot be located upon the exercise of due diligence;
b. has been transferred or sold to, or deposited with, a third party;
c. has been placed beyond the jurisdiction of the court;
d. has been substantially diminished in value; or
e. has been commingled with other property which cannot be divided without difficulty;

it is the intent of the United States of America, pursuant to Title 21, United States Code, Section 853(p), as incorporated by Title 28, United States Code, Section 2461(c), to seek forfeiture of any other property of the defendant up to the value of the property subject to forfeiture, that is $61,753.

(All in violation of Title 21, United States Code, Sections 334(d)(3), 853(p) and Title 28, United States Code, Section 2461(c)).

A TRUE BILL.

PRESIDING JUROR

Indictment returned: 6/26/2019

For SCOTT C. BLADER
United States Attorney