



U.S. Department of Justice

United States Attorney
District of New Jersey
970 Broad Street, Suite 700
Newark, New Jersey 07102

(973) 645-2700

November 6, 2018

Walter F. Brown, Esq.
Orrick, Herrington & Sutcliffe LLP
The Orrick Building
405 Howard Street
San Francisco, CA 94105-2669

Re: Plea Agreement with Hisao Yabe

Dear Mr. Brown:

This letter sets forth the plea agreement between the United States Attorney for the District of New Jersey and the United States Department of Justice, by and through the Consumer Protection Branch (collectively, the "United States") and your client, Hisao Yabe. The offer of the United States to enter into this plea agreement will expire on November 9, 2018, if it is not accepted in writing by that date.

Charge

Conditioned on the understandings specified below, the United States will accept a guilty plea from Hisao Yabe to an Information which charges him with the introduction into interstate commerce of a medical device that was misbranded (pursuant to 21 U.S.C. § 352(t)(2)) in violation of the Federal Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. §§ 331(a) and 333(a)(1). If Hisao Yabe enters a guilty plea and is sentenced on this charge, and if Hisao Yabe otherwise fully complies with all of the terms of this agreement, the United States will not initiate any further criminal charges against Hisao Yabe with respect to communications by Olympus Corporation or its subsidiaries or any employees or other representatives of such entities concerning adverse events or regulatory issues involving the TJF-Q180V duodenoscope between January 2012 and January 2016. However, in the event that a guilty plea in this matter is not entered for any reason or the judgment of conviction entered as a result of this guilty plea does not remain in full force and effect, Hisao Yabe agrees that any dismissed charges and

any other charges that are not time-barred by the applicable statute of limitations on the date this agreement is signed by Hisao Yabe may be commenced against Hisao Yabe, notwithstanding the expiration of the limitations period after Hisao Yabe signs the agreement.

Sentencing

The violation of Title 21, United States Code, Sections 331(a) and 333(a)(1) to which Hisao Yabe agrees to plead guilty carries a statutory maximum term of imprisonment of one year and a statutory maximum fine equal to the greatest of: (1) \$100,000; (2) twice the gross amount of any pecuniary gain that any persons derived from the offense; or (3) twice the gross amount of any pecuniary loss sustained by any victims of the offense. See Title 18, United States Code, Sections 3581(b)(6), 3571(b)(5), 3571(d). Fines imposed by the sentencing judge may be subject to the payment of interest.

The sentence to be imposed upon Hisao Yabe is within the sole discretion of the sentencing judge, subject to the provisions of the Sentencing Reform Act, 18 U.S.C. §§ 3551-3742, and the sentencing judge's consideration of the United States Sentencing Guidelines. The United States Sentencing Guidelines are advisory, not mandatory. The sentencing judge may impose any reasonable sentence up to and including the statutory maximum term of imprisonment and the maximum statutory fine. The United States cannot and does not make any representation or promise as to what guideline range may be found by the sentencing judge, or as to what sentence Hisao Yabe ultimately will receive.

Further, in addition to imposing any other penalty on Hisao Yabe, the sentencing judge (1) will order Hisao Yabe to pay an assessment of \$25 pursuant to 18 U.S.C. § 3013, which assessment must be paid by the date of sentencing; (2) may order Hisao Yabe to pay restitution pursuant to 18 U.S.C. §§ 3663 et seq.; and (3) pursuant to 18 U.S.C. § 3583, may require Hisao Yabe to serve a term of supervised release of not more than one year, which will begin at the expiration of any term of imprisonment imposed. Should Hisao Yabe be placed on a term of supervised release and subsequently violate any of the conditions of supervised release before the expiration of its term, Hisao Yabe may be sentenced to not more than one year's imprisonment in addition to any prison term previously imposed, regardless of the statutory maximum term of imprisonment set forth above and without credit for time previously served on post-release supervision, and may be sentenced to an additional term of supervised release.

Restitution

The United States agrees that it will not seek a restitution order as to Hisao Yabe as part of the resolution of the charges in the Information. While

violations of the FDCA create risk of patient harm, direct and proximate harm to specific persons from Hisao Yabe's offense conduct has not been established so as to provide for a restitution order.

Rights of the United States Regarding Sentencing

Except as otherwise provided in this agreement, all parties to this agreement reserve their rights to correct any misstatements relating to the sentencing proceedings, and to provide the sentencing judge and the United States Probation Office all law and information relevant to sentencing, favorable or otherwise. In addition, the United States may inform the sentencing judge and the United States Probation Office of: (1) this agreement; and (2) the full nature and extent of Hisao Yabe's activities and relevant conduct with respect to this case.

Stipulations

The United States and Hisao Yabe agree to stipulate at sentencing to the statements set forth in the attached Schedule A and Schedule B, which hereby are made a part of this plea agreement. This agreement to stipulate, however, cannot and does not bind the sentencing judge, who may make independent factual findings and may reject any or all of the stipulations entered into by the parties. To the extent that the parties do not stipulate to a particular fact or legal conclusion, each reserves the right to argue the existence of and the effect of any such fact or conclusion upon the sentence. Moreover, this agreement to stipulate on the part of the United States is based on the information and evidence that the United States possesses as of the date of this agreement. Thus, if the United States obtains or receives additional evidence or information prior to sentencing that it determines to be credible and to be materially in conflict with any stipulation in the attached Schedule A or Schedule B, the United States shall not be bound by any such stipulation. A determination that any stipulation is not binding shall not release either the United States or Hisao Yabe from any other portion of this agreement, including any other stipulation. If the sentencing court rejects a stipulation, both parties reserve the right to argue on appeal or at post-sentencing proceedings that the sentencing court was within its discretion and authority to do so. These stipulations do not restrict the Government's right to respond to questions from the Court and to correct misinformation that has been provided to the Court.

Immigration Consequences

Hisao Yabe understands that, if he is not a citizen of the United States, his guilty plea to the charged offense may result in him being subject to immigration proceedings and removed from the United States by making him

deportable, excludable, or inadmissible, or ending his naturalization. The defendant understands that the immigration consequences of this plea will be imposed in a separate proceeding before the immigration authorities. The defendant wants and agrees to plead guilty to the charged offense regardless of any immigration consequences of this plea, even if this plea will cause him removal from the United States. The defendant understands that he is bound by his guilty plea regardless of any immigration consequences of the plea. Accordingly, the defendant waives any and all challenges to his guilty plea and to his sentence based on any immigration consequences, and agrees not to seek to withdraw his guilty plea, or to file a direct appeal or any kind of collateral attack challenging his guilty plea, conviction, or sentence, based on any immigration consequences of his guilty plea.

Other Provisions

This agreement is limited to the United States Attorney's Office for the District of New Jersey and the United States Department of Justice, Consumer Protection Branch, and cannot bind other federal, state, or local authorities. However, the United States will bring this agreement to the attention of other prosecuting offices, if requested to do so.

This agreement was reached without regard to any civil or administrative matters that may be pending or commenced in the future against Hisao Yabe. This agreement does not prohibit the United States, any agency thereof (including the Internal Revenue Service and Immigration and Customs Enforcement), or any third party from initiating or prosecuting any civil or administrative proceeding against Hisao Yabe.


No provision of this agreement shall preclude Hisao Yabe from pursuing in an appropriate forum, when permitted by law, an appeal, collateral attack, writ, or motion claiming that Hisao Yabe received constitutionally ineffective assistance of counsel.

No Other Promises

This agreement hereto constitutes the plea agreement between Hisao Yabe and the United States and supersedes any previous agreements between them. No additional promises, agreements, or conditions have been made or will be made unless set forth in writing and signed by the parties.

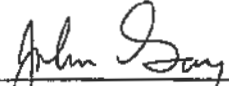
Very truly yours,

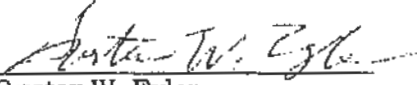
RACHAEL HONIG
Attorney for the United States
Acting Under Authority Conferred by
28 U.S.C. § 515


By: ~~JACOB T. ELBERG~~
R. DAVID WALK, JR.
Assistant U.S. Attorneys

PATRICK JASPERSE
Senior Litigation Counsel
Consumer Protection Branch
U.S. Department of Justice

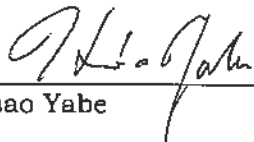
APPROVED:


John Gay
Chief, Criminal Division
U.S. Attorney's Office
District of New Jersey


Gustav W. Eyster
Acting Director
U.S. Department of Justice
Consumer Protection Branch

I have received this letter from my attorney, Walter F. Brown, Esquire. It has been translated for me into Japanese. I have read this letter. My attorney and I have discussed the letter and all of its provisions, including the provisions addressing the charge, sentencing, restitution, forfeiture, the stipulations, waiver, and immigration consequences. I understand the letter fully. I hereby accept the terms and conditions set forth in this letter and acknowledge that it constitutes the plea agreement between the parties. I understand that no additional promises, agreements, or conditions have been made or will be made unless set forth in writing and signed by the parties. I want to plead guilty pursuant to this plea agreement.

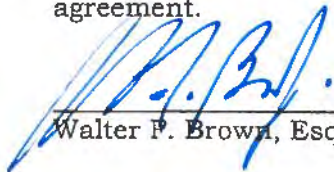
AGREED AND ACCEPTED:



Hisao Yabe

Date: Nov. 9, 2018

I have discussed with my client this plea agreement and all of its provisions, including those addressing the charge, sentencing, restitution, forfeiture, the stipulations, waiver, and immigration consequences. My client understands the letter fully and wants to plead guilty pursuant to this plea agreement.



Walter F. Brown, Esquire

Date: 11/12/18

Plea Agreement with Hisao Yabe

Schedule A

1. This Office and Hisao Yabe recognize that the United States Sentencing Guidelines are not binding upon the Court. This Office and Hisao Yabe nevertheless agree to the stipulations set forth herein.
2. The version of the United States Sentencing Guidelines effective November 1, 2018, applies in this case.
3. The guideline that applies to the charged conduct is U.S.S.G. § 2N2.1, which provides for a base offense level of 6. See U.S.S.G. § 2N2.1(a).
4. As of the date of this letter, Hisao Yabe has clearly demonstrated a recognition and affirmative acceptance of personal responsibility for the offense charged. Therefore, a downward adjustment of 2 levels for acceptance of responsibility is appropriate if Hisao Yabe's acceptance of responsibility continues through the date of sentencing. See U.S.S.G. § 3E1.1(a).
5. In accordance with the above, the parties agree that the total Guidelines offense level applicable to Hisao Yabe is 4 (the "agreed total Guidelines offense level").
6. Hisao Yabe reserves the right to move for a downward departure or variance under 18 U.S.C. § 3553(a). The United States reserves the right to oppose such a motion. The United States reserves the right to move for an upward departure or for a variance under 18 U.S.C. § 3553(a). Hisao Yabe reserves the right to oppose such a motion or argument.
7. Hisao Yabe knows that he has and, except as noted below in this paragraph, voluntarily waives, the right to file any appeal, any collateral attack, or any other writ or motion, including but not limited to an appeal under 18 U.S.C. § 3742 or a motion under 28 U.S.C. § 2255, which challenges the sentence imposed by the sentencing court if that sentence falls within or below the Guidelines range that results from the agreed total Guidelines offense level of 4. This Office will not file any appeal, motion or writ which challenges the sentence imposed by the sentencing court if that sentence falls within or above the Guidelines range that results from the agreed total Guidelines offense level of 4. The parties reserve any right they may have under 18 U.S.C. § 3742 to appeal the sentencing court's determination of the criminal history category. The provisions of this paragraph are binding on the parties even if the Court employs a Guidelines analysis different from that stipulated to herein. Furthermore, if the sentencing court accepts a stipulation, both parties

waive the right to file an appeal, collateral attack, writ, or motion claiming that the sentencing court erred in doing so.

8. Both parties reserve the right to oppose or move to dismiss any appeal, collateral attack, writ, or motion barred by the preceding paragraph and to file or to oppose any appeal, collateral attack, writ or motion not barred by the preceding paragraph.

Schedule B

The United States and Hisao Yabe agree to stipulate to the following facts:

(a) During the time period of the offense conduct, Hisao Yabe was Olympus Medical Systems Corporation's ("OMSC") Division Manager for the Quality and Environment Division – the top position in OMSC's Division that consists of several departments, including the Regulatory Affairs & Quality Assurance ("RA/QA") Department, which had responsibility for filing certain Medical Device Reports ("MDRs") regarding OMSC medical devices with the U.S. Food and Drug Administration ("FDA"). Hisao Yabe was aware of and was directly involved in certain aspects of OMSC's response to infections involving the Olympus TJF-Q180V duodenoscope ("Q180V"). Hisao Yabe was aware of and was directly involved in certain aspects of what OMSC communicated to the FDA about issues surrounding the Q180V. Hisao Yabe was aware of the obligation to supplement MDRs under certain circumstances, and was involved in OMSC's failure to supplement MDRs.

(b) On or about May 25, 2012, OMSC filed an MDR concerning 16 patients at Erasmus Medical Center ("Erasmus") in the Netherlands who were infected with *Pseudomonas aeruginosa* after the same Q180V duodenoscope was used on them. *Pseudomonas aeruginosa* was detected in a sample collected from the device.

(c) In or around August 2012, OMSC, including Hisao Yabe, received an English translation of "Investigation Report on Scope G-206" by Dr. Arjo Loeve of Delft University of Technology ("the Delft Report"), which reported on the results of inspecting and dismantling the Olympus TJF-Q180V duodenoscope used on the patients at Erasmus Medical Center.

(d) The Delft Report included information which was required to be included in a supplemental MDR. OMSC was required to supplement the initial MDR regarding the Erasmus adverse events within 30 days of receiving the Delft Report, but did not do so.

(e) Hisao Yabe and other OMSC employees considered whether to supplement the Erasmus MDR for reasons unrelated to the Delft Report in 2013, but a supplemental report was not filed by OMSC until 2015.