

U.S. DISTRICT COURT
N.D. OF N.Y.
FILED

APR 24 2007

LAWRENCE K. BAERMAN, CLERK
ALBANY

IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF NEW YORK

UNITED STATES OF AMERICA

v.

Criminal Action No.

07-CR-202 (FJS)

PLEA AGREEMENT

JAMES A. HOLLAND,

Defendant.

GLENN T. SUDDABY, United States Attorney for the Northern District of New York (by Supervisory Assistant U.S. Attorney Grant C. Jaquith, appearing) and JAMES A. HOLLAND (with Gaspar M. Castillo, Jr., Esq., appearing) hereby enter into the following Plea Agreement regarding the disposition of certain criminal charges against the Defendant:

1. In return for the consideration described below, JAMES A. HOLLAND agrees to enter a plea of guilty to a one-count Information charging him with wrongfully and unlawfully failing

to establish and maintain adequate and accurate cases histories on patients participating in drug studies for which he was the principal investigator, a misdemeanor violation of 21 U.S.C. §§ 331(e) and 333(a)(1).

2. Potential Penalties. JAMES A. HOLLAND understands that his guilty plea to Count 1 will subject him to the following potential penalties:

a. Maximum term of imprisonment: 1 year. (21 U.S.C. § 333(a)(1))

b. Supervised Release: In addition to imposing any other penalty, the sentencing Court may require the Defendant to serve a term of supervised release of up to 1 year, to begin at the expiration of any term of imprisonment imposed upon him. (18 U.S.C. § 3583). Should the Defendant be placed on a term of supervised release and subsequently violate any of the terms and conditions of that release before the expiration of such term, he may be sentenced to up to 1 year imprisonment in addition to any prison term previously imposed upon him and in addition to the statutory maximum term of imprisonment set forth above. Under some circumstances, the Court may also extend the term of supervised release, and it may modify, reduce, or enlarge the conditions of such release.

c. Maximum fine: \$100,000. (18 U.S.C. § 3571).

d. Mandatory Restitution: Pursuant to the Mandatory Victim Restitution Act, the sentencing Court must order that the Defendant pay restitution to any victim of the offense of conviction who has suffered physical injury or pecuniary loss. (18 U.S.C. § 3663A).

e. Special Assessment: The Defendant will be required to pay an assessment of \$25, which is due and payable at the time of sentencing. (18 U.S.C. § 3013). The Defendant

agrees to deliver a check or money order to the Clerk of the Court in the amount of \$25, payable to the U.S. District Court, at the time of his sentencing.

f. Interest and penalties: Interest and penalties may accrue, as a matter of law, on any unpaid financial obligation imposed as part of the Defendant's sentence, from as early as the date of sentencing.

3. JAMES A. HOLLAND understands that the sentence to be imposed upon him is within the discretion of the sentencing Court, subject to the statutory maximum penalties and the provisions of the Sentencing Reform Act and the United States Sentencing Guidelines promulgated thereunder, as modified by *United States v. Booker*, 543 U.S. 220 (2005). In imposing the sentence, the Court must take into account the Sentencing Guidelines, along with the other factors set forth in 18 U.S.C. § 3553(a). While the Court is not ultimately bound to impose a sentence within the applicable Sentencing Guidelines range, its sentence must be reasonable based upon consideration of all relevant sentencing factors.

4. Elements of the Offense. JAMES A. HOLLAND understands the following legal elements of the offense stated in Count 1, and admits that those elements accurately describe his criminal conduct:

a. The defendant was conducting a clinical investigation of a new drug pursuant to an investigational new drug application on file with the Food and Drug Administration;

b. The defendant was responsible for establishing and maintaining adequate and accurate case histories on each individual administered the drug or employed as a control in the investigation;

c. Adequate and accurate case histories on each individual administered the drug or employed as a control in the investigation were not established and maintained;

d. The defendant failed to act on his authority to ensure that adequate and accurate case histories on each individual administered the drug or employed as a control in the investigation were established and maintained, and prevent or correct violations.

5. Factual Basis for the Plea. JAMES A. HOLLAND admits the following facts, which establish his guilt on the offense stated in Count 1:

a. The FDA Approval Process

i. The United States Food and Drug Administration (“FDA”), an agency of the United States, is responsible for protecting the health and safety of the public by enforcing the Federal Food, Drug, and Cosmetic Act (“FDCA”) and its implementing regulations. The FDA’s responsibilities under the FDCA include regulating the manufacture, labeling, and distribution of all drugs shipped or received in interstate commerce, including drugs intended solely for investigational use. Under the FDCA and its implementing regulations, a pharmaceutical manufacturer (“drug sponsor”) must apply to the FDA for approval to market new drugs, and was required to demonstrate, often through clinical investigations, the safety and effectiveness of a drug before approval is given. As part of the process of deciding whether a new drug should be approved for marketing, FDA examines the design and conduct of the clinical studies as well as the results.

ii. Prior to commencing any clinical study, a sponsor is generally required by FDA regulations to provide the FDA with extensive information regarding the proposed study, including a detailed investigation plan known as the “study protocol.” The study protocol contains information about how the clinical study will be conducted, where studies will be done and by

whom, how the drug's safety and effectiveness will be evaluated, and what findings would require the study to be changed or halted.

iii. Drug sponsors typically hire qualified physicians, known as clinical investigators, to carry out the actual clinical studies of the drug on human subjects, hereinafter referred to as “study subjects.” Each physician participating in a drug study as an investigator must sign FDA Form 1572 in which the physician commits to conduct the study in accordance with the study protocol, to personally conduct or supervise the investigation and to comply with FDA regulations.

iv. Under Title 21, United States Code, Section 355(i), the FDA is authorized to issue regulations requiring the establishment and maintenance of records relating to the investigational use of new drugs. These regulations impose specific record-keeping requirements upon clinical investigators. When submitted to the FDA as part of a new drug application, these records are part of the basis for the FDA's evaluation of the drug's safety and effectiveness and the agency's determination as to whether the drug can be approved for marketing. Under 21 C.F.R. § 312.62(a), a clinical investigator is required to maintain adequate records of the disposition of investigational new drugs, including the use by subjects. Under 21 C.F.R. § 312.62(b), a clinical investigator is required to maintain adequate and accurate case histories relating to the clinical use of investigational new drugs, including case report forms and supporting data such as the medical records of individuals administered the investigational drug or employed as a control in the investigation. Under Title 21, United States Code, Section 331(e), it is unlawful for any person to fail to establish or maintain any record required under Title 21, United States Code, Section 355(i), including those records required under 21 C.F.R. 312.62(a) and (b).

v. Although persons enrolled as study subjects are volunteers, a drug sponsor is not necessarily permitted to allow all those willing to volunteer to participate in its clinical studies. Whether an individual may participate depends on whether that individual meets certain criteria, which are set forth in the applicable study protocol and based, in part, on the drug under investigation and how that drug is thought to be useful. The criteria for patient selection are aimed at ensuring that appropriate patients are studied, both so undue risks to patients are avoided and the study results are valid. Study protocols thus provide that only patients who agreed and formally consented by signing an informed consent form and fulfilled all the inclusion/exclusion criteria were eligible for admission to the study, with exceptions to the protocol requiring the agreement of the sponsor. During the course of a drug study, and in accordance with the study protocol, study subjects are administered the study drug or a placebo and visit regularly with the investigator so that the data that are required to be submitted to the FDA can be collected and evaluated.

vi. Information about each study subject, including the subject's medical history, laboratory results, and reaction to the drug under study, is provided to the drug sponsor upon completion of a drug study, who in turn may provide the information to the FDA for use in its evaluation of whether the drug should be approved for human use.

vii. One procedure commonly used to conduct a clinical study is called a comparative, randomized, open-label, multi-center study (hereinafter referred to as "comparative study"). Generally, in a comparative study, the new drug is given to certain members of the defined test group, while a second drug, designed to treat the same symptoms, is given to other members of the defined test group.

viii. A procedure called “randomization” is used, whereby either the new drug or the second drug is randomly assigned to be taken by each study subject. At the end of the study, the raw data is supplied to a statistician, who uses mathematical formulas to determine whether the clinical trial has shown the new drug to be safe and effective when compared with the second drug. The statistician’s analysis is then incorporated into a report made to the FDA together with the other data developed during the drug study.

b. Stratton VA Medical Center

i. The Stratton Veterans Affairs Medical Center, located in Albany, New York, is part of the VA Healthcare Network Upstate New York, within the Veterans Health Administration of the United States Department of Veterans Affairs. The Department of Veterans Affairs (DVA) is a department of the United States (in the executive branch of the government). The Stratton VA Medical Center provides veterans with inpatient and outpatient medical care, including radiation oncology. The Stratton VA Medical Center has been designated as a Comprehensive Cancer Center.

ii. The Albany Research Institute, Inc., is a non-profit research and education corporation established to conduct research projects and education activities in connection with the Stratton VA Medical Center.

c. The defendant, JAMES A. HOLLAND, is a licensed physician. Beginning in 1989, the defendant, JAMES A. HOLLAND, was employed by the Department of Veterans Affairs. Beginning in August of 1998, the defendant, JAMES A. HOLLAND, was employed by the Department of Veterans Affairs at the Stratton VA Medical Center in the oncology program. In June of 2000, JAMES A. HOLLAND became the head of the oncology program at the Stratton VA

Medical Center. His duties in this position included directing, controlling, managing, and supervising the oncology research program, which included pharmaceutical protocols, adherence to system standards, and compliance with research requirements.

d. Tax 325 Study

i. Aventis Pharmaceuticals, Inc. (“Aventis”)(formerly Rhone-Poulenc Rorer Pharmaceuticals, Inc.) was a pharmaceutical company engaged in developing, testing, and marketing pharmaceutical products, including docetaxel, also known by the brand name of taxotere, developed by Aventis for the treatment of respiratory tract infections.

ii. Aventis sponsored an open label, randomized multicentre phase II/III study of docetaxel in combination with cisplatin (CDDP) or docetaxel in combination with 5-flourouracil (5-FU) and CDDP compared to the combination of CDDP and 5-FU in patients with metastatic or locally recurrent gastric cancer previously untreated with chemotherapy for advanced disease. The protocol number for the study was RP 56976-V-325; it sometimes was referred to as Tax 325.

iii. The Coalition of National Cancer Cooperative Groups, Inc., conducts clinical research services on behalf of or supported by commercial or government sponsors, and did so for Aventis in connection with Tax 325.

iv. The agreement for the Tax 325 Study provided for a grant of \$5,000 for each completed, eligible, and evaluated patient/subject, scheduled as follows:

- When patient is randomized \$1,666
- After patient has completed half of study \$1,667
- After close-out \$1,667

v. The Stratton VA Medical Center was a participating site in the Tax 325 study. The defendant, JAMES A. HOLLAND, was the principal investigator for the Tax 325 study at the Stratton VA Medical Center and signed an FDA Form 1572 in which he committed to conducting the study in accordance with the study protocol, to personally conduct or supervise the investigation, and to comply with FDA regulations.

vi. The study population for Tax 325 was patients with metastatic or locally recurrent gastric cancer previously untreated with chemotherapy for advanced disease. The inclusion criteria for Aventis' Tax 325 study protocol included requirements that each patient had levels of creatinine, total bilirubin, AST (SGOT), and alkaline phosphatase within specified levels, and set a minimum calculated creatinine clearance of 60 ml/mn.

e. Tax 327 Study

i. Aventis also sponsored a multicenter phase III randomized trial comparing docetaxel administered either weekly or every three weeks in combination with prednisone versus mitoxantrone in combination with prednisone for metastatic hormone refractory prostate cancer. The protocol number for the study was RP56976V-327; it sometimes was referred to as Tax 327.

ii. The clinical investigation agreement for the Tax 327 Study, dated February 28, 2000, provided that all work in the study would be performed in accordance with the terms of the protocol, instructions by the sponsor, good clinical practice, generally accepted professional standards of care, and all applicable laws and regulations. The agreement provided for payment of a maximum of \$75,000 on a pro rata basis for 10 patients completing the study, as follows:

iii. 10% once all required regulatory documents were submitted to the sponsor and approved and the study was initiated;

iv. 25% once 3 patients were enrolled and completed case report forms for baseline and cycle 1 for these patients were reviewed and forwarded to the sponsor, another 25% once the number reached 6 patients, and another 25% once the number reached 9 patients; and,

v. 15% once completed case report forms (through follow-up) for 10 patients were retrieved and forwarded to the sponsor. An amendment on April 25, 2001 upped the number of patients to 25 and the maximum payment to \$192,500.

vi. The Stratton VA Medical Center also was a participating site in the Tax 327 study. The defendant, JAMES A. HOLLAND, was the principal investigator for the Tax 327 study at the Stratton VA Medical Center and signed an FDA Form 1572 in which he committed to conducting the study in accordance with the study protocol, to personally conduct or supervise the investigation, and to comply with FDA regulations.

f. DFMO Study

i. ILEX Oncology, Inc., and the National Cancer Institute (NCI), Division of Cancer Prevention (DCP), co-sponsored a phase III, randomized, double-blind study to compare the use of difluoromethylornithine (DFMO) to the use of a placebo in treating low grade superficial bladder cancer according to the time to the first recurrence of a bladder tumor and toxicities. Patients who met all of the eligibility requirements were randomly assigned a treatment and registered in the study by sending an informed consent document and laboratory normal values to ILEX and faxing a registration form to a foundation which forwarded it by fax to ILEX. Case Report Forms (CRFs) were supplied by ILEX, and were to be filled out completely and returned.

ii. The clinical investigation agreement for the DFMO Study, dated March 10, 2000, provided that the study would be performed in accordance with the protocol, instructions by the sponsor, good clinical practice, generally accepted professional standards of care, and all applicable laws and regulations. The agreement provided for payment of \$2,500 per qualified, evaluable patient, with \$625 paid upon receipt of registration documents, \$1,250 paid when each qualified, evaluable patient completed or discontinued early from the one-year treatment period of the study and the required study documents (CRFs) were received and reviewed by the sponsor, and the remaining \$625 paid when each qualified, evaluable patient completed or discontinued early from the first year of follow-up and the required study documents (CRFs) were received and reviewed by the sponsor. The requirements for payment included that procedures were performed in full compliance with the protocol, the data submitted be complete and accurate, and the patient have met the inclusion and exclusion criteria.

iii. The Stratton VA Medical Center also was a participating site in the DFMO study. The defendant, JAMES A. HOLLAND, was the principal investigator for the DFMO study at the Stratton VA Medical Center and signed an FDA Form 1572 in which he committed to conducting the study in accordance with the study protocol, to personally conduct or supervise the investigation, and to comply with FDA regulations.

g. From about 1999, Paul H. Kornak was employed at the Stratton Veterans Affairs Medical Center, Albany, New York, first by Albany Research Institute, Inc., initially as a Research Assistant and then as Study Director of VA Cooperative Studies, and then by the Department of Veterans Affairs (at the Stratton Veterans Affairs Medical Center) as a Program Specialist, with duties which included coordination of research protocols. Under the supervision of

the defendant, **JAMES A. HOLLAND**, Kornak was responsible for liaison planning, organizing, coordinating, implementing, directing, integrating, controlling, and evaluating research elements in the oncology research program, which included VA Cooperative Studies and pharmaceutical protocols, as well as data management, adherence to system standards, and compliance with research requirements. Under the supervision of the defendant, **JAMES A. HOLLAND**, Kornak was the site coordinator at the Stratton VA Medical Center for the Tax 325, Tax 327, and DFMO studies.

h. From on or about May 14, 1999, up to and including on or about July 10, 2002, in the Northern District of New York, the defendant, **JAMES A. HOLLAND**, did, in connection with leading, supervising, managing, conducting, and coordinating clinical trials and studies at the Stratton VA Medical Center, including the Tax 327, Tax 325, and the DFMO studies, wrongfully and unlawfully fail to establish and maintain adequate and accurate case histories of some individuals administered investigational drugs and employed as controls in the studies, in that the case histories included materially false documentation and/or information provided by a subordinate, Paul H. Kornak, that enabled persons to be enrolled as study subjects who did not qualify under the study protocol. Case histories for such patients contained false and misleading documents, including some which falsely reflected:

- That patients had blood drawn on certain dates;
- Laboratory analysis of samples from study subjects;
- That study subjects had electrocardiograms done on certain dates;
- The results of electrocardiograms of study subjects;
- The results of ejection fraction testing; and,
- A false radiology display report; and,

- Dates on a final surgical pathology report, a letter, an operative note, urethrocytogram retrograde supervision and interpretation report, and a urology clinic progress note.

The above described false and misleading documents were created and submitted by a direct subordinate of the defendant, JAMES A. HOLLAND. The defendant, JAMES A. HOLLAND, had the responsibility, authority, and duty to ensure that adequate and accurate case histories were maintained and promptly detect and correct inadequate and inaccurate cases histories, but wrongfully and unlawfully failed to do so, including by failing to review or check the accuracy of the above described case histories and reports of laboratory analysis, electrocardiograms, ejections fraction testing, radiology reports, surgical reports, and operative and progress notes. One example was the defendant, JAMES A. HOLLAND, causing to be administered to James J. DiGeorgio the chemotherapeutic drugs docetaxel, cisplatin, and 5-FU in connection with Tax 325 on or about May 31, 2001, based upon documents and records made by Kornak which falsely stated and represented the results of blood chemistry analysis of a sample provided by James J. DiGeorgio on May 25, 2001. The false documents purported that James J. DiGeorgio met the inclusion and exclusion criteria for participation in Tax 325 when the actual results did not meet the inclusion and exclusion criteria and showed impaired kidney and liver function. The defendant, JAMES A. HOLLAND, did not review the actual report of laboratory analysis or check the accuracy of the documents and records made by Kornak, and James J. DiGeorgio thus was administered the chemotherapeutic drugs. James J. DiGeorgio died on or about June 11, 2001.

6. The Defendant understands that the sentencing Court may make factual findings with respect to any and all sentencing factors and issues, including those referenced in the United States

Sentencing Guidelines, whether or not such factors or issues have been admitted by the Defendant or stipulated by the parties. In making those findings by a preponderance of the evidence, the Court may consider any reliable evidence, including hearsay. The Defendant agrees that his sentence may be determined based upon such judicial fact-finding.

7. The Defendant agrees that the statements made by him in signing this Agreement, including the factual admissions set forth above shall be admissible and useable against the Defendant by the United States in any subsequent criminal or civil proceeding, even if he fails to enter a guilty plea pursuant to this Agreement, or if such a guilty plea is later vacated or withdrawn. The Defendant waives any rights under Fed. R. Crim. P. 11(f) and Fed. R. Evid. 410, to the extent these rules are inconsistent with this paragraph or with this Agreement generally.

8. In order to facilitate the collection of financial obligations to be imposed in connection with this prosecution, the Defendant agrees fully to disclose all assets in which he has any interest or over which the Defendant exercises control, directly or indirectly, including those held by a spouse, nominee or other third party. The Defendant will promptly submit a completed financial statement to the U.S. Attorney's Office, in a form it provides and as it directs. The Defendant promises that his financial statement and disclosures will be complete, accurate and truthful.

9. In exchange for the plea of guilty to Count 1 by JAMES A. HOLLAND and his continuing compliance with all of the terms of this Plea Agreement, the United States Attorney's Office for the Northern District of New York agrees as follows:

a. It will bring no further federal criminal charges against the Defendant relating

to the conduct committed before the date of this Agreement which is described in Count 1 and the Defendant's admissions above.

b. If the guilty plea to Count 1 is later withdrawn or vacated, the charges not prosecuted pursuant to subparagraphs 9a and 9b of this Agreement may be prosecuted, notwithstanding the expiration of the statute of limitations between the signing of this Agreement and the reinstatement of any such charges. The Defendant waives any defense or objection to the prosecution of any such charges that are not time-barred by the applicable statute of limitations as of the date of this Agreement.

c. It reserves the right to recommend a specific sentence within the applicable Guidelines range determined by the Court.

d. The U.S. Attorney's Office reserves the right to advise the sentencing Court and the Probation Office of any information, in aggravation or mitigation of sentencing, whether or not encompassed within Count 1.

10. The U.S. Attorney's Office and JAMES A. HOLLAND agree to stipulate at sentencing to the statements set forth in the subparagraphs below. It is understood, however, that the agreement to stipulate cannot and does not bind the sentencing Court, which may make independent factual findings by a preponderance of the evidence and reject any or all stipulations presented by the parties. Such a determination that a stipulation is not binding on the Court will not be the basis for the withdrawal of a plea of guilty by the Defendant, and will not release either the U.S. Attorney's Office or the Defendant from any other portion of this Agreement, including any other stipulations agreed to herein. To the extent the stipulations below do not reflect agreement on any factor or issue potentially affecting the advisory Sentencing Guidelines range applicable to the

Defendant, the Defendant and the U.S. Attorney's Office each expressly reserves the right to advocate if, and how, any such factor or issue would apply under the Sentencing Guidelines.

a. If the Defendant demonstrates “acceptance of responsibility” for the offense through the time of sentencing, the U.S. Attorney’s Office will recommend a 2-level downward adjustment to the applicable Sentencing Guidelines range, pursuant to U.S.S.G. § 3E1.1(a).

b. The Defendant’s Criminal History Category cannot be definitively determined prior to the completion of the presentence investigation.

11. The Defendant asserts that his conduct was merely negligent, warranting a downward departure pursuant to U.S.S.G. § 2N2.1, comment. (n. 1). The United States asserts that death resulted from the offense, warranting an upward departure pursuant to U.S.S.G. § 2N2.1, comment. (n. 3). The Defendant and the U.S. Attorney's Office each expressly reserves the right to oppose the aforementioned assertion of the other and advocate if, and how, any such factor or issue would apply under the Sentencing Guidelines.

12. Should the U.S. Attorney’s Office determine that the Defendant, after the date of this Plea Agreement, (i) has committed any further crime or violated any condition of release or supervision imposed by the Court (whether or not charged); or (ii) has breached any condition of this Agreement, the U.S. Attorney's Office will have the right, in its sole discretion, to void this Agreement, in whole or in part. In the event of any such breach, the Defendant will not be permitted to withdraw his guilty plea under this Agreement, but will thereafter be subject to prosecution for any federal criminal violation of which the U.S. Attorney’s Office has knowledge, including but not limited to charges that this Office has agreed not to prosecute in subparagraphs 9a and 9b of this Agreement.

a. The Defendant waives any defense or objection to the commencement of any such prosecution that is not time-barred by the applicable statute of limitations as of the date of this Agreement, notwithstanding the expiration of the statute of limitations between the signing of this Agreement and the commencement of any such prosecution.

b. Moreover, in connection with any such prosecution, any information, statement, or testimony provided by the Defendant, and all leads derived therefrom, may be used against him, without limitation. The Defendant waives any rights under Fed. R. Crim. P. 11(f) and Fed. R. Evid. 410, to the extent these rules are inconsistent with this paragraph or with this Agreement generally.

c. In the event of any such breach by the Defendant, the U.S. Attorney's Office will have the right, in its sole discretion, to do the following, notwithstanding any contrary provision or stipulation in this Plea Agreement:

i. to advocate if, and how, any particular adjustment or specific offense characteristic affects the applicable Sentencing Guidelines range;

ii. to utilize any information, statement, or testimony provided by the Defendant in determining the applicable Sentencing Guidelines range, notwithstanding U.S.S.G. § 1B1.8;

iii. to recommend a specific sentence of imprisonment within or above the applicable Sentencing Guidelines range determined by the Court.

13. This Agreement is limited to the U.S. Attorney's Office for the Northern District of New York and cannot bind other federal, state or local prosecuting authorities. Furthermore, this

Agreement does not prohibit the United States, any agency thereof, or any third party from initiating or prosecuting any civil or administrative proceedings directly or indirectly involving the Defendant.

14. The Court is neither a party to, nor bound by this Agreement. The Court may accept or reject this Plea Agreement or defer a decision until it has considered the Presentence Investigation Report prepared by the U.S. Probation Office.

a. If the Court rejects the provisions of this Agreement permitting the Defendant to plead guilty to Count 1 in satisfaction of other potential charges, which provisions were negotiated pursuant to Fed. R. Crim. P. 11(c)(1)(A), the Court will afford the Defendant an opportunity to withdraw his plea of guilty prior to sentencing, pursuant to Fed. R. Crim. P. 11(c)(5) & (d).

b. The Court is not bound by any recommendation, stipulation, or request made by the parties, pursuant to Fed. R. Crim. P. 11(c)(1)(B), as to the appropriate sentence, and the Defendant may not withdraw his plea of guilty if the Court declines to follow any such recommendation, stipulation, or request. The U.S. Attorney's Office reserves the right to support and defend, in connection with any post-sentencing proceedings, any decision the Court may make with regard to the Defendant's sentence, whether or not such decision is consistent with this Office's recommendations, stipulations, or requests.

15. The Defendant acknowledges that he has read each of the provisions of the entire Plea Agreement with the assistance of counsel and understands its provisions.

a. The Defendant understands his right to assistance of counsel at every stage of the proceeding and has discussed his constitutional and other rights with defense counsel. The Defendant understands that by entering a plea of guilty, he will be giving up his rights (i) to be presumed innocent until proven guilty beyond a reasonable doubt; (ii) to plead not guilty; (iii) to trial

by jury; (iv) to confront, cross-examine, and compel the attendance of witnesses at trial; (v) to present evidence in his defense; and (vi) to remain silent and refuse to be a witness against himself by asserting the privilege against self-incrimination.

b. The Defendant has been advised by defense counsel of the nature of the charges to which he is entering a guilty plea and the nature and range of the possible sentence. The Defendant understands the sentencing Court's obligation to consider the United States Sentencing Guidelines (as explained further above) and the Court's discretion to depart from those Guidelines under some circumstances or otherwise to impose a reasonable sentence outside of the applicable Sentencing Guidelines range.

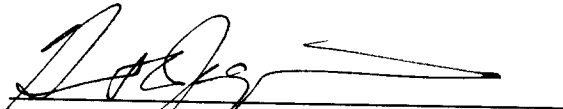
16. Waiver of Appeal and Collateral Attack. The Defendant acknowledges that, after consultation with defense counsel, he fully understands the extent of his rights to appeal, and/or to collaterally attack the conviction and sentence in this case, including by a challenge based upon *United States v. Booker*, 543 U.S. 220 (2005) and its progeny. The Defendant waives any and all rights, including those conferred by 18 U.S.C. § 3742 and/or 28 U.S.C. § 2255, to appeal or collaterally attack his conviction and any sentence of imprisonment of 6 months or less, including any related issues with respect to the establishment of the advisory Sentencing Guidelines range or the reasonableness of the sentence imposed. The Defendant acknowledges that the number of months specified above is not a promise of any particular sentence and is not binding on the Court. The Defendant agrees that, should the sentence imposed exceed 6 months, this would not permit him to withdraw his guilty plea or to appeal or collaterally attack his conviction, but would merely allow the Defendant to appeal or collaterally attack the sentence imposed by the Court, to the extent permitted by 18 U.S.C. § 3742 and/or 28 U.S.C. § 2255.

17. No promises, agreements or conditions have been entered into other than those set forth in this Agreement, and none will be entered into unless memorialized in writing and signed by all parties. This Agreement, to become effective, must be signed by all of the parties listed below.

GLENN T. SUDDABY
United States Attorney
Northern District of New York

Dated: April 24, 2007

By:



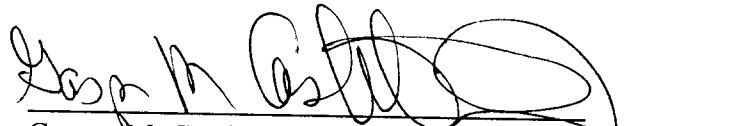
Grant C. Jaquith
Assistant U.S. Attorney
Chief, Criminal Division
Bar Roll No. 501396

Dated: April 24, 2007



JAMES A. HOLLAND
Defendant.

Dated: April 24, 2007



Gaspar M. Castillo, Jr., Esq.
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