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

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UNITED STATES OF AMERICA

Criminal Action No.

v. 07-CR-202 (FJS)

JAMES A. HOLLAND,

Defendant.

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SENTENCING MEMORANDUM OF THE UNITED STATES

Dated: March 17, 2008

Respectfully submitted,

GLENN T. SUDDABY
United States Attorney

/s/ *Grant C. Jaquith*
By: Grant C. Jaquith
Assistant U. S. Attorney
Chief, Criminal Division
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I. INTRODUCTION

On April 24, 2007, pursuant to an Agreement between the parties, the Defendant, Dr. James A. Holland, entered a plea of guilty to a one-count Information charging him with the misdemeanor offense of wrongfully and unlawfully failing to fulfill his responsibility, authority, and duty to ensure that adequate and accurate case histories of individuals administered investigational drugs and employed as controls in cancer treatment studies were maintained, and promptly detect and correct inadequate and inaccurate cases histories, in violation of Title 21, United States Code, Sections 331(e) and 333(a)(1). The United States submits this Memorandum pursuant to the Order issued by the Court in anticipation of sentencing, which now is scheduled for April 9, 2008.

This Memorandum addresses the Presentence Investigation Report and the objections and arguments relating to sentencing made by the Defendant to date. If the Court is considering a departure from the applicable U.S. Sentencing Guidelines range, or the imposition of a non-Guidelines sentence, on a ground not previously identified by the parties or in the Presentence Investigation Report, the parties are entitled to notice and an opportunity to respond. *United States v. Anati*, 457 F.3d 233, 237 (2d Cir. 2006) (requiring notice of and an opportunity to comment on the court's intent to impose, *sua sponte*, a non-Guidelines sentence in order to prevent unfair surprise and allow for the "adversarial testing of factual and legal considerations relevant to sentencing"). *See* Fed R. Crim. P. 32(i)(1)(c), 32 (h).

II. PLEA AGREEMENT

The following stipulations in the Plea Agreement ("PA") executed by the parties in this

case relate to the calculation of the Sentencing Guidelines range:

The statutory maximum term of imprisonment is 1 year (PA ¶ 2a);

"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)."(PA ¶ 10a.); and

"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." (PA ¶ 11).

III. PRESENTENCE REPORT

A. Factual Findings

The United States generally adopts the facts set forth in the Presentence Investigation Report submitted by the United States Probation Office. One issue has been spotted since the sentencing conference: Paragraph 24 of the Report reflects that Aventis Pharmaceuticals suffered a loss of $192,000, but the information the United States received from victims reflected a loss by Aventis of $ 488,907.58.

B. Calculation of the Sentencing Guidelines Range

The United States previously expressed no objection to the offense level computations,

the criminal history score, and the resulting Sentencing Guidelines range set forth in the Presentence Investigation Report, but the amount of loss by Aventis affects the offense level computation by two levels, the United States would calculate the adjustments for the large number of vulnerable victims under different guidelines provisions, and there is an issue regarding whether the cross reference to U.S.S.G. § 2B1.1 should be applied, as explained below.

The Presentence Investigation Report finds that the base offense level is determined under U.S.S.G. § 2B1.1(a)(2), by cross reference from § 2N2.1(b)(1), because the offense involved fraud. Section 2N2.1(b)(1) provides: "If the offense involved fraud, apply § 2B1.1." The application notes to section 2N2.1 echo subsection (b)(1). The defendant's base offense level under U.S.S.G. § 2B1.1(a)(2) is 6, as it would be under § 2N2.1(a). The Presentence Investigation Report adds 18 levels for specific offense characteristics, per U.S.S.G. § 2B1.1(b). With a 2 level increase for the defendant's role in the offense (U.S.S.G. § 3B1.3) and a 3 level decrease for acceptance of responsibility (U.S.S.G. § 3E1.1), the defendant's total offense level is 23, his criminal history category is I, and his Guideline sentence is the statutory maximum of imprisonment for 12 months, per (U.S.S.G. § 5G1.1(a)). (Without the statutory maximum, the Guideline imprisonment range calculated in the Presentence Investigation Report would be 46 - 57 months).

1. ***Whether Section 2B1.1 Should Be Applied***

The defendant has challenged the application of three specific offense characteristics under U.S.S.G. § 2B1.1(b): an increase of 12 levels because the offense involved a loss of over $200,000 [§ 2B1.1(b)(1)(G)]; an increase of 4 levels because the offense "involved 50 or more victims" [§ 2B1.1(b)(2)(B)]; and an increase of 2 levels because the offense involved "the

conscious or reckless risk of death or serious bodily injury." [§ 2B1.1(b)(12)(A)]. The Addendum to the Presentence Investigation Report addresses the defendant's contentions and reaffirms the guideline calculations.

The defendant argues that the application of the fraud guideline is in contravention of the plea agreement. However, the plea agreement sets forth no agreement regarding the applicable offense level, including whether the cross-reference to U.S.S.G. § 2B1.1 should apply, because there was no such agreement. Negotiations focused on whether the defendant would acknowledge accountability for the death of James J. DiGeorgio, and not on other offense characteristics or guidelines issues. No agreement was reached, so the sentencing stipulations include only those spelled out above concerning acceptance of responsibility and criminal history category. Other issues were left to be governed by this part of paragraph 10 of the plea agreement: "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."

The Presentence Investigation Report reflects the conclusion that the defendant's failure to maintain accurate patient records defrauded the pharmaceutical companies of the money they invested to fund the cancer treatment studies compromised by the defendant's failure to fulfill his responsibility, duty, and obligation. That the defendant's malfeasance cost the pharmaceutical companies their investment in the compromised studies is irrefutable. Whether that fact means "the offense involved fraud,"as Section 2N2.1(b)(1) requires to cross reference Section 2B1.1, is less certain.

U.S.S.G. § 1B1.3(a) provides that cross references are determined on the basis of relevant conduct, including the acts and omissions of the defendant and "all harm that resulted from the acts and omissions." *See, e.g., United States v. Speelman*, 431 F.3d 1226, 1231 (9th Cir. 2005). *See generally United States v. Johnson*, 507 F.3d 793, 797 (2d Cir. 2007)(affirming a sentence to life imprisonment upon conviction of a firearms offense by cross-referencing the murder guideline based upon acquitted conduct); *United States v. Cordoba-Murgas*, 233 F.3d 704 (2d Cir. 2004)(directing that the preponderance standard be applied to determine whether relevant conduct justified cross-referencing the murder guideline under U.S.S.G. § 2D1.1(d)(1)).

In this case, the harm that resulted from Dr. Holland's acts and omissions included the fraud (and, more significantly, the death of James J. DiGeorgio, as is addressed *infra*). Dr. Holland pled guilty to violating Title 21, United States Code, Sections 331(e) and 333(a)(1), by wrongfully and unlawfully failing to establish and maintain adequate and accurate case histories of patients administered investigational drugs and employed as controls in cancer treatment studies for which he was responsible. Dr. Holland did not admit any intent to defraud or mislead, for which Section 333(a)(2) would have called for a felony punishment (with a maximum term of imprisonment for 3 years). But Dr. Holland did admit that he "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 [] case histories and reports of laboratory analysis, electrocardiograms, ejections fraction testing, radiology reports, surgical reports, and operative and progress notes," which included materially false documentation and information provided by his direct subordinate, Paul H. Kornak.

Kornak pled guilty to making and using a materially false statement (18 U.S.C. § 1001), mail fraud (18 U.S.C. §§ 1341 and 1346), and criminally negligent homicide (New York Penal Law § 125.10 and 18 U.S.C. § 3), and was sentenced principally to be imprisoned for 71 months. Kornak participated in a scheme to defraud the sponsors of clinical trials and studies, the Albany Research Institute, Inc., the Stratton VA Medical Center, United States Department of Veterans Affairs, and citizens of the United States of their right to his honest services, and to obtain money and property from the sponsors, Albany Research Institute, Stratton VA Medical Center, and Department of Veterans Affairs by means of false and fraudulent pretenses, representations, and promises, in that he would and repeatedly did submit false documentation regarding patients and study subjects and enroll and cause to be enrolled persons as study subjects who did not qualify under the particular study protocol.

The interplay of the law regarding the offense of conviction and Dr. Holland's malfeasance clouds as much as clarifies the indication by the relevant guideline provisions that the defendant's offense level should be determined by cross-reference to the fraud guideline. The federal Food, Drug, and Cosmetic Act, which includes 21 U.S.C. §§ 331(e) and 333(a)(1), has been interpreted as establishing a sort of strict liability for the safe handling of food and drugs. *See* Nicholas Freitag, *Federal Food and Drug Act Violations*, 41 AM. CRIM. L. REV. 647, 653 (2004). In *United States v. Dotterweich*, 320 U.S. 277, 64 S.Ct. 134, 88 L.Ed. 48 (1943), the Supreme Court declared that the Act "touch[es] phases of the lives and health of people which . . . are largely beyond self-protection," and thus

> dispenses with the conventional requirement for criminal conduct – awareness of some wrongdoing. In the interest of the larger good it puts the burden of acting at hazard upon a person otherwise

> innocent but standing in responsible relation to a public danger.

320 U.S. at 280-81, 64 S.Ct. at 136. Individuals "who have a responsible share in the furtherance of the transaction which the statute outlaws" are accountable for offenses against the safety of food and drugs without consciousness of wrongdoing. *Id*., 320 U.S. at 284, 64 S.Ct. at 138. In *United States v. Park*, 421 U.S. 658, 95 S.Ct. 1903, 44 L.Ed.2d 489 (1975), the Court elaborated that the Act holds

> criminally accountable the persons whose failure to exercise the authority and personal responsibility reposed in them by the business organization resulted in the violation complained of.

421 U.S. at 671, 95 S.Ct. at 1911. Moreover,

> the Act imposes not only a positive duty to seek out and remedy violations when they occur but also, and primarily, a duty to implement measures that will ensure that violations will not occur. The requirements of foresight and vigilance imposed on responsible corporate agents are beyond question demanding, and perhaps onerous, but they are no more stringent than the public has the right to expect of those who voluntarily assume positions of authority in business enterprises whose services and products affect the health and well-being of the public that supports them.

Id., 421 U.S. at 672, 95 S.Ct. at 1911. What is required of responsible officials who have the power to prevent or correct violations is "the highest standard of foresight and vigilance," not "that which is objectively impossible." *Id.*, 421 U.S. at 673, 95 S.Ct. at 1912.

By his guilty plea, Dr. Holland has admitted that he completely failed to meet this standard. Though a responsible official subject to strict liability who was merely negligent might avoid the cross reference for fraud and even obtain a downward departure, *see* U.S.S.G. § 2N2.1, comment. (n.1), Dr. Holland's misconduct is not at the margin of the expanse of what is criminalized by the Act. Dr. Holland violated an express duty known and willingly undertaken,

not one fairly implied. Section 331(e) explicitly proscribes the failure to maintain records in accordance with statutory requirements, and the statutes and regulations detail that accurate case histories are included. As principal investigator for the Tax 327, Tax 325, and DFMO studies, Dr. Holland attested, on FDA Forms 1572 for each study, to his commitment: to conduct the studies in accordance with their protocols, to personally conduct or supervise the investigations, to ensure that those assisting in conducting the studies are informed of their obligations, and "to maintain adequate and accurate records in accordance with 21 CFR 312.62."[1]

Dr. Holland completely failed to fulfill both that personal commitment and his individual statutory obligation. As a consequence, the case histories for his 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;
- A false radiology display report; and,
- Dates on a final surgical pathology report, a letter, an operative note, urethrocystogram retrograde supervision and interpretation report, and a urology clinic progress note.

[1] 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.

Dr. Holland's reckless management of these cancer treatment studies is best illustrated by his response when ILEX monitors discovered altered documents for patient "ELK"on a site visit January 10-11, 2002. It ultimately was determined that Kornak had altered surgical pathology reports, a letter from a urologist to Stratton VA Medical Center, and a hospital operative note, all by changing July dates to dates in April; altered the hospital operative note by adding "Retrograde pyleogram revealed no abnormality of the upper urinary tract;" falsely made a Glens Falls Hospital urethrocystogram retrograde supervision and interpretation report dated 7/12/2001 regarding ELK, where the actual procedure was done at the Stratton VA Medical Center on another patient on another day; and altered a urology clinic progress note by changing: "Cystoscopy performed 11/08/01 revealed a small <2mm lesion which unfortunately was not biopsied. This may have represented a small recurrence of tumor," to: "Cystoscopy performed 11/08/01 revealed no masses seen in the urinary bladder." In January of 2002, an ILEX monitor advised Dr. Holland of her concerns regarding documents pertaining to patient ELK and "concerns about Dr. Paul Kornak's behavior." Dr. Holland defended Kornak as "well experienced." In April of 2002, Dr. Holland told the monitor that Kornak had admitted adding the "retrograde pyleogram" information to the hospital operative note. And yet, in a letter dated May 28, 2002, to the ILEX Senior Director of Quality Assurance, Dr. Holland defended the study and Kornak by arguing that the questioned documents were found in the shadow chart, rather than the official medical record, and

> were not copies of actual source documents, but rather information placed by the Coordinator pending receipt of the source documents. Their purpose was to provide evidence that he had checked the entry criteria. The Coordinator **due to inexperience** assumed that he would receive the requested source documents as

> indicated by the outside providers, and proceeded with the protocol

(emphasis supplied). Dr. Holland went on to claim, in the letter, that

> to demonstrate that all entry criteria had been checked . . . [Kornak] produced a temporary form (urethrocystogram report, dated 7/12/01) based upon the information he had obtained to place in the shadow chart until he received the official report at a later date.

Under the circumstances, recasting Kornak's fraudulent conduct as an effort to document authentic information on a "temporary form" and attributing it to inexperience was disingenuous.

Kornak's position was that Dr. Holland's exhortation to enroll more patients in the cancer treatment studies motivated him to falsify records, and that Dr. Holland had to have known because he knew from the actual patient records and laboratory results that patients were enrolled who were ineligible. Paragraph 23 of the Presentence Investigation Report reflects a more direct accusation – that Kornak manipulated study data "at the demand of [Dr. Holland, who] told Kornak who was to be tested or not tested and who would be included in or not included in the trials and studies." Kornak apparently never spoke with Dr. Holland about falsifying records, and the United States is aware of no direct evidence that he urged or even knew of the specific fraudulent conduct as Kornak was committing it. But this crime was committed over a three year period, with many obviously altered documents involving a large number of cancer patients needing careful attention because of the gravity of their conditions. In some cases, such as alterations of laboratory reports submitted to pharmaceutical companies or placed in local files, the accurate information was provided directly to Dr. Holland. Whether Dr. Holland's complete failure to fulfill his statutory, regulatory, employment, professional, and moral duty, responsibility, and obligation was a product of conscious avoidance or reckless disregard of what

was occurring, it is clear that application of the fraud guideline yields a more accurate measure of the gravity of Dr. Holland's malfeasance by accounting for the harm that resulted from his omissions. It is not quite as clear that "the offense involved fraud," such that the cross reference applies.

_____2. ***The Loss Amount***

The Pre-sentence Investigation Report provides for an increase of 12 levels, per U.S.S.G. § 2B1.1(b)(1)(G), because the offense involved a loss of over $200,000. The information the United States received from victims reflected a loss by Aventis Pharmaceuticals, Inc., of $ 488,907.58 and a loss by ILEX Oncology, Inc., of $ 14,017.47, which would be a total of $492,925.05, and would yield an increase of 14 levels, per § 2B1.1(b)(1)(H), or 2 more than scored in the Report. The total offense level would be 25, with a corresponding imprisonment range of 57 - 71 months, but the guideline sentence would remain 12 months (under U.S.S.G. § 5G1.1(a)).

_____3. ***The Offense Involved A Large Number of Vulnerable Victims***

The investigation by the Department of Veterans Affairs Office of Inspector General uncovered altered documents for a total of 65 patients who participated in studies at the Stratton VA Medical Center. Adding the Department of Veteran's Affairs, Aventis, ILEX, and Genentech[2] , the total number of victims is 69. However, the number for which Dr. Holland is accountable should be 23, comprised of the 4 entities and 19 patients – 13 in the Tax 327 study, 3 in the Tax 325 study, 2 in the DFMO study, plus 1 in a study sponsored by Genentech. The

[2] Genetech, Inc., sponsored a "clinical trial to evaluate the efficacy and safety of rhuMAb VEGF (bevacizumab)in combination with standard chemotherapy in subjects with metastatic colorectal cancer." Dr. Holland was the principal investigator.

remaining patients were in studies for which Dr. Holland was not the principal investigator – 38 in the FeAST[3] study and 8 in the PIVOT[4] study.

U.S.S.G. § 2B1.1(b)(2)(B) provides for an increase of 4 levels if the offense involved 50 or more victims. For 10 or more victims, § 2B1.1(b)(2)(A) provides for an increase of 2 levels. However, in the context of U.S.S.G. § 2B1.1, the definition of "victim" is set forth in Application Note 1 as follows:

> "Victim" means (A) any person who sustained any part of the actual loss determined under subsection (b)(1); or (B) any individual who sustained bodily injury as result of the offense.

U.S.S.G. § 2B1.1, comment. (n. 1). Application Note 3 defines "actual loss" as "the reasonably foreseeable pecuniary harm that resulted from the offense." U.S.S.G. § 2B1.1, comment. (n. 3). The restrictive definition of "victim" that applies to the scoring under U.S.S.G. § 2B1.1 does not count the patients who did not sustain a financial loss or a provable bodily injury as a result of the offense. If such patients are not counted, the number of victims under U.S.S.G. § 2B1.1 is less than 50 for all studies and may be less than 10 for the cancer studies.

An increase of the defendant's offense level remains appropriate because "the defendant knew or should have known that a victim of the offense was a vulnerable victim." U.S.S.G. § 3A1.1(b)(1). The commentary to Section 3A1.1 explains that, "[f]or purposes of subsection (b), a 'vulnerable victim' means a person (A) who is a victim of the offense of conviction and any conduct for which the defendant is accountable under § 1B1.3 (Relevant Conduct); and (B) who

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[3] FeAST the name given to VA Cooperative Study # 410, the Iron (Fe) and Atherosclerosis Study (AST), testing a new procedure for controlling hardening of the arteries.

[4] PIVOT is an acronym for the Prostrate Cancer Intervention Versus Observation Trial conducted as a VA Cooperative Study.

is unusually vulnerable due to age, physical or mental condition, or who is otherwise particularly susceptible to the criminal conduct." U.S.S.G. § 3A1.1, comment. (n. 2). The commentary then gives as an example of when the adjustment applies a situation similar to this one: "in a fraud case in which the defendant marketed an ineffective cancer cure." *Id.*

The 2-level increase provided by U.S.S.G. § 3A1.1(b)(1) applies if **any one victim** is vulnerable. *United States v. Crispo,* 306 F.3d 71, 83 (2d Cir. 2002). It is beyond cavil that Mr. DiGeorgio was a vulnerable victim. Mr. DiGeorgio was suffering from terminal gastric cancer, a fact well known to the defendant. Though he consented to participation in the Tax 325 treatment study, Mr. DiGeorgio was not told that he was ineligible to participate because his liver and kidney functions were too poor to tolerate the chemotherapeutic agents. To the contrary, Mr. DiGeorgio was encouraged to participate in the study. That participation caused Mr. DiGeorgio's death. The 2-level increase under U.S.S.G. § 3A1.1(b)(1) thus should be applied.

Under U.S.S.G. § 3A1.1(b)(2), the offense level is increased by two more if "the offense involved a large number of vulnerable victims." Neither the guideline nor its commentary specify a threshold number which qualifies as large. Here, the 19 veterans who were afflicted with cancer and subjects in the cancer treatment studies for which Dr. Holland was directly responsible may be classified as vulnerable. All 65 of the veterans who had altered records – 27 afflicted with cancer and participants in cancer treatment studies and 38 participants in the atherosclerosis study (FeAST) – may be classified as vulnerable. In at least the 19 cases, the defendant's malfeasance undermined the reliability and usefulness of the studies which were conducted to advance medical care and help others, left the veterans susceptible to treatment based on inaccurate information, and risked the dire consequences illustrated by the death of Mr.

DiGeorgio.. Even though the economic impact of the defendant's fraud was on Aventis, ILEX, and the Department of Veteran's Affairs, "an enhancement for vulnerable victim is appropriate where the exploitation of patients is part of the scam." *United States v. Echevarria*, 33 F.3d 175, 179 (2d Cir.1994), citing *United States v. Bachynshy*, 949 F.2d 722, 735-36 (5th Cir. 1991), *cert. denied*, 506 U.S. 850 (1992). As in *Echevarria* and *Bachynshy,* these patients "were unwitting instrumentalities" of fraud. *United States v. Echevarria*, 33 F.3d at 179.

Without an enhancement under U.S.S.G. § 2B1.1(b)(2)(B), the enhancement under U.S.S.G. § 3A1.1(b)(2) may be applied. *See* U.S.S.G. § 2B1.1, comment. (n. 4(D))("If subsection (b)(2)(B) . . . applies, an enhancement under § 3A1.1(b)(2) shall not apply."). Applying U.S.S.G. § 3A1.1(b)(1) and (2) to calculation of Dr. Holland's offense level under the cross reference and using larger loss amount would yield a total offense level of 25, with a corresponding guideline imprisonment range of 57 - 71 months but a guideline sentence of 12 months. Applying the enhancement to calculation of Dr. Holland's offense level under U.S.S.G. § 2N2.1(a) would yield a total offense level of 8 and a guideline imprisonment range of 0 - 6 months.

IV. MOTIONS, APPLICATIONS AND REQUESTS OF THE UNITED STATES

A. Motion for Additional Reduction for Acceptance of Responsibility

Pursuant to U.S.S.G. § 3E1.1(b), if the Defendant's offense level is 16 or greater, the United States moves for an additional (third) offense level reduction for "acceptance of responsibility." The Defendant timely notified the authorities of his intention to plead guilty, thereby permitting the U.S. Attorney's Office to avoid preparing for trial and permitting the government and the Court to allocate their resources efficiently.

B. Motion for Upward Departure Based On the Death of James J. DiGeorgio

Application note 3(A) to U.S.S.G. § 2N2.1 provides that an upward departure may be warranted if death results from a regulatory offense, and cites Chapter Five, Part K of the Guidelines. Guidelines § 5K2.1 provides that "[i]f death resulted, the court may increase the sentence above the authorized Guideline range." The discussion of factors to be considered under § 5K2.1 includes "the extent to which the offense level for the offense of conviction, as determined by the other Chapter Two guidelines, already reflects the risk of personal injury." Whether Dr. Holland's base offense level is derived from U.S.S.G. § 2N2.1(a) or (b)(cross referencing § 2B1.1), neither contemplates death, and Section 5K2.1 specifically declares that "a substantial increase may be appropriate . . . if the underlying offense was one for which base offense levels do not reflect an allowance for the risk of personal injury, such as fraud." The gravity of the effect of the defendant's criminal conduct calls for a substantial increase in his sentence, and the United States moves for an upward departure, and asks the Court to impose sentence at or near the statutory maximum of imprisonment for 12 months.

If the cross-reference to § 2B1.1 is followed, Dr. Holland is subject to the increase of 2 levels because the offense involved "the conscious or reckless risk of death or serious bodily injury,"per U.S.S.G. § 2B1.1(b)(12)(A), as found in the Presentence Investigation Report, and an upward departure may be appropriate because the "offense caused or risked substantial non-monetary harm." U.S.S.G. § 2B1.1, comment. (n.19(A)(I)). Whichever path is chosen, each leads to imposition of the maximum term of imprisonment (12 months) based upon the death of James J. DiGeorgio.

As Dr. Holland admitted in connection with his guilty plea, one example of his failure to

review or check the accuracy of case histories, reports of laboratory analysis, surgical reports, and operative and progress notes, was his:

> 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.

As Dr. Holland admitted, he "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," and died on June 11, 2001.

Kornak made several false documents reflecting Mr. DiGeorgio's situation: a Form B.10, "Blood Chemistry/Hematology/Calculated Creatinine Clearance/Coagulation," which falsely represented Mr. DiGeorgio's blood chemistry on May 25, 2001; and an emergency triage assessment dated 5/25, a laboratory report which stated and represented the results of serum analysis on 05/25/2001, and an after care instruction sheet dated 05/25/2001 from Albany Medical Center, which were false in that Mr. DiGeorgio was not seen at Albany Medical Center on May 25, 2001, and there was no serum analysis for Mr. DiGeorgio done at Albany Medical Center on May 25, 2001. On the blood chemistry form, Kornak falsified test results for creatinine, alkaline phosphotase, AST (SGOT), bilirubin, and calculated creatinine clearance to make it appear that Mr. DiGeorgio met the inclusion and exclusion criteria for participation in Tax 325. The true blood chemistry results were outside the study criteria, and showed that Mr.

DiGeorgio had significantly impaired kidney and liver function which rendered him ineligible for administration of the prescribed combination and dose of chemotherapeutic drugs – because there was an unacceptable risk that those drugs would be lethal to someone with such impaired kidney and liver function. But Kornak falsified the test results, Mr. DiGeorgio was enrolled in the study, administered the drugs, and died within days. Though Mr. DiGeorgio had advanced gastric cancer, and likely had only a few months to live, the evidence shows that he would not have died on June 11, 2001, if he had not been subjected to the infusion of the chemotherapeutic drugs on May 31st. If Kornak had not falsified the test results, Mr. DiGeorgio would not have been enrolled in the study, infused on May 31st, and died on June 11th. Mr. DiGeorgio and his family could have considered and made an informed decision regarding other treatment options or seeking hospice care.

Kornak's deplorable crime hardly absolves Dr. Holland – it underscores the magnitude of Dr. Holland's malfeasance. Dr. Holland had done absolutely nothing to ensure that accurate case histories or patient records were maintained. But his responsibility for the death of Mr. DiGeorgio rests not only on that failure, but on one far more directly causal and reckless: As the treating physician and oncologist, Dr. Holland received the actual results of Mr. DiGeorgio's blood chemistry analysis directly from the hospital laboratory, **but did not look at them**. Had Dr. Holland looked at the results, he would have seen that Mr. DiGeorgio's levels of creatinine, alkaline phosphotase, AST (SGOT), and bilirubin, and his calculated creatinine clearance, all were outside the criteria for participation in the study, and showed that he had significantly impaired kidney and liver function which rendered him ineligible, and known that administration of the prescribed combination and dose of chemotherapeutic drugs posed an unacceptable risk of

death. Dr. Holland caused the chemotherapeutic drugs docetaxel, cisplatin, and 5-FU to be administered to Mr. DiGeorgio in connection with Tax 325 on May 31, 2001, without reviewing the actual report of laboratory analysis or checking the accuracy of the documents and records made by Kornak. Dr. Holland's failure to establish and maintain an adequate and accurate case history and patient record thus led to Mr. DiGeorgio's death, warranting a sentence that includes imprisonment for 12 months.

C. Ex Parte Communications With The Court

The United States respectfully requests that the Court provide the parties with any ex parte communications received by the Court in connection with the sentencing in this case, with the exception of the confidential sentencing recommendations submitted by the United States Probation Office.

D. Payment of Financial Obligations

The imposition of an order requiring payment of restitution in full, according to a schedule set by the Court, is mandatory pursuant to 18 U.S.C. §§ 3663A(c)(1)(A) and 3664(f), as agreed to in ¶ 2d of the Plea Agreement.

We respectfully request that the Court order immediate payment, in full, of the special assessment, restitution, and any fine imposed.

V. UNITED STATES' RECOMMENDATION WITHIN GUIDELINES RANGE

In determining a sentence consistent with the Supreme Court's guidance in *United States*

v. Booker, 543 U.S. 220, 259-260 (2005), the Court must consider the Sentencing Guidelines, along with the other factors set forth in 18 U.S.C. § 3553(a). *United States v. Rattoballi*, 452 F.3d 127, 132 (2d Cir. 2006). The Sentencing Reform Act

> requires judges to consider the Guidelines "sentencing range established for . . . the applicable category of offense committed by the applicable category of defendant," [18 U.S.C.] § 3553(a)(4), the pertinent Sentencing Commission policy statements, the need to avoid unwarranted sentencing disparities, and the need to provide restitution to victims, §§ 3553(a)(1), (3), (5)-(7) (main ed. and Supp. 2004). And the Act . . . requires judges to impose sentences that reflect the seriousness of the offense, promote respect for the law, provide just punishment, afford adequate deterrence, protect the public, and effectively provide the defendant with needed educational or vocational training and medical care. § 3553(a)(2) (main ed. and Supp. 2004) * * *.

Booker, 543 U.S. at 259-260.

The United States respectfully contends that a sentence of imprisonment for 12 months would be "sufficient, but not greater than necessary," to take into account all of the relevant sentencing factors. 18 U.S.C. § 3553(a).

VI. PROCEDURAL REQUIREMENTS FOLLOWING *BOOKER*

A. Calculation of the Guidelines Range

The court "should begin all sentencing proceedings by correctly calculating the applicable guidelines range." *Gall*, 128 S. Ct. at 596 (2007). "An error in determining the applicable Guideline range . . . would be the type of procedural error that could render a sentence unreasonable under *Booker*." *United States v. Selioutsky*, 409 F.3d 114, 118 (2d Cir. 2005), *citing United States v. Rubenstein*, 403 F.3d 93, 98-99 (2d Cir.), *cert. denied*, 546 U.S. 876 (2005).

Prior to sentencing, the Court must resolve any material issues of fact, and must state its factual findings – by adoption of the Presentence Report or otherwise – on the record in a manner sufficient to permit appellate review. *See, e.g., United States v. Jeffers,* 329 F.3d 94, 101-02 (2d Cir. 2003); *United States v. Ben-Shimon,* 249 F.3d 98, 103 (2d Cir. 2001). The Court is authorized to make all factual determinations relating to the Sentencing Guidelines by a preponderance of the evidence, considering any reliable evidence, including hearsay. *See United States v. Gonzalez*, 407 F.3d 118, 125 (2d Cir. 2005) (the power of district judges to resolve disputed facts by a preponderance of the evidence at sentencing survives *Booker*); *United States v. Martinez*, 413 F.3d 239, 243 (2d Cir. 2005) (neither *Booker* nor *Crawford v. Washington*, 541 U.S. 36 (2004), bars judicial consideration of hearsay at sentencing), *cert. denied,* 546 U.S. 1117 (2006); *United States v. Crosby*, 397 F.3d 103, 112, 113 (2d Cir. 2005). "A sentencing judge would . . . violate [18 U.S.C. §] 3553(a) by limiting consideration of the applicable Guidelines range to the facts found by the jury or admitted by the defendant, instead of considering the applicable Guidelines range, as required by subsection 3553(a)(4), based on the facts found by the court." *Crosby,* 397 F.3d at 115.

B. Consideration of the Sentencing Guidelines and the § 3553(a) Factors

Although the Sentencing Guidelines are no longer mandatory, "*Booker* did not signal a return to wholly discretionary sentencing." *Rattoballi*, 452 F.3d at 132. The Second Circuit has cautioned:

> [I]t would be a mistake to think that, after *Booker/Fanfan*, district judges may return to the sentencing regime that existed before 1987 and exercise unfettered discretion to select any sentence within the applicable statutory maximum and

> minimum. On the contrary, the Supreme Court expects sentencing judges faithfully to discharge their statutory obligation to "consider" the Guidelines and all of the other factors listed in section 3553(a). We have every confidence that the judges of this Circuit will do so, and that the resulting sentences will continue to substantially reduce unwarranted disparities while now achieving somewhat more individualized justice.

Crosby, 397 F.3d at 113-114.

"As a matter of administration and to secure nationwide consistency, the Guidelines should be the starting point and the initial benchmark" for a sentence. *Gall*, 128 S. Ct. at 596. The Guidelines, which were fashioned after careful consideration of the other § 3553(a) factors, "cannot be called just another factor in the statutory list, 18 U.S.C. § 3553(a), because they are the only integration of the multiple factors and, with important exceptions, their calculations were based upon the actual sentences of many judges." *Rattobolli*, 452 F.3d at 133 (citations and internal quotation marks omitted); *Gall*, 128 S. Ct. at 594 (Guidelines are "the product of careful study based on extensive empirical evidence derived from the review of thousands of individual sentencing decisions").

C. Statement of Reasons for the Sentence

Section 3553(c) requires the district court, "at the time of sentencing," to "state in open court the reasons for its imposition of the particular sentence." "[W]hen a judge decides simply to apply the Guidelines to a particular case, doing so will not necessarily require a lengthy explanation." *Rita*,

127 S. Ct. at 2469. Still, "[w]here a prosecutor or defendant presents non-frivolous reasons for imposing a different sentence, . . . the judge will normally . . . explain why he has rejected those

arguments." *Id*.

Greater specificity is required for: (1) sentences within a Guidelines range that exceeds 24 months – for which the court must state "the reason for imposing a sentence at a particular point within the range" (18 U.S.C. § 3553(c)(1)); and (2) sentences outside the Guidelines range – for which the court must state orally and in the written judgment "the specific reason" for the imposition of the sentence (18 U.S.C. § 3553(c)(2)). *See*, *e.g.*, *United States v. Lewis*, 424 F.3d 239, 249 (2d Cir. 2005) (remanding because, in imposing a sentence for supervised release violation, the district court failed to state sufficient reasons for imposing a sentence outside the range recommended by Guidelines policy statements); *United States v. Goffi*, 446 F.3d 319, 321-22 (2d Cir. 2006) (remanding for the district court to amend the written judgment to state the specific reason for the imposition of a sentence outside of the policy statement for a probation violation).

When a sentence deviates significantly from the Guidelines, and the judge has not made a compelling statement of reasons, the Second Circuit "may be forced to vacate" if "the record is insufficient, on its own, to support the sentence as reasonable." *Rattoballi*, 452 F.3d at 135.

> Judicial decisions are reasoned decisions. Confidence in a judge's use of reason underlies the public's trust in the judicial institution. A public statement of those reasons helps provide the public with the assurance that creates that trust.

Rita, 127 S. Ct. 2468.

VII. UNITED STATES' POSITION REGARDING REMAND

Pursuant to the provisions of 18 U.S.C. § 3143(b), the United States respectfully moves the Court for an order directing remand of the Defendant immediately after sentence.

VIII. CONCLUSION

The United States respectfully contends that the recommended sentence of imprisonment for 12 months is the most appropriate, because it is "sufficient, but not greater than necessary" to achieve the goals of sentencing. If the Court adopts the Guidelines calculations in the Presentence Investigation Report, or adjusts them to reflect the increased loss amount and different way of accounting for the large number of vulnerable victims, the United States respectfully requests that the Court also grant the motion for an upward departure as an alternative basis for the sentence.