
PUBLIC COMMENT

2008 AMENDMENT CYCLE



March 28, 2008



U.S. Department of Justice
Criminal Division

Office of the Assistant Attorney General

Washington, DC 20530-0001

March 27, 2008

The Honorable Ricardo H. Hinojosa
Chair, U.S. Sentencing Commission
One Columbus Circle, NE
Suite 2-500, South Lobby
Washington, DC 20002-8002

Dear Judge Hinojosa:

On behalf of the Department of Justice, we submit the following comments regarding the proposed amendments to the federal sentencing guidelines and issues for comment published in the Federal Register in January 2008. We appreciate the opportunity to comment upon these amendments and look forward to continuing to work with the Commission on these and other issues that will arise during the next year to ensure a fair sentencing guidelines system.

1. Repromulgation of the Emergency Disaster Fraud Amendment

Congress passed the *Emergency and Disaster Assistance Fraud Penalty Enhancement Act of 2007*, Pub. L. 110-179, on December 19, 2007, and it was signed into law by the President on January 7, 2008. The Commission promulgated an emergency amendment, effective February 6, 2008, that responded to the directive in section five of the Act. We believe that emergency amendment should now be made permanent with certain changes.

At a public hearing on February 13, 2008, United States Attorney David Dugas outlined the Department of Justice's views on the amendment and the issues for comment presented by the Commission in the *Proposed 2008 Guideline Amendments*. In his testimony, Mr. Dugas explained that the Act was passed to reverse the perception by some that they could make fraudulent claims in emergency situations, remain undetected and, even if caught, go relatively unpunished. As Senator Sessions noted at the time the bill was passed, "We need to make it clear that those who steal that money are going to be prosecuted more vigorously and punished more severely than somebody who commits some other kind of crime because I think it is worse to steal from the generosity of the American people who intended to help those in need." S. Rep. 110-69, at 4-5 (2007). In passing the Act, Congress recognized that, unlike conventional frauds involving routine

government benefits where the harm from fraudulent applications is generally dispersed over time and not particularly visible in its effects, disaster fraud schemes can cause immense and widespread harm in a short span of time. The concerns raised by Congress are reflected in the increased penalties for these offenses.

In response to this legislation, the Commission took a significant first step in addressing the concerns by including as part of the emergency amendment a specific offense characteristic (SOC) directing a two-level increase "[i]f the offense involved fraud or theft involving any benefit authorized, . . . in connection with a declaration of a major disaster or emergency." U.S.S.G. § 2B1.1(b)(16). This SOC, however, would rarely result in a sentence of imprisonment and is therefore insufficient in many cases to achieve the goals of sentencing in 18 U.S.C. § 3553 or Congressional intent.¹

We believe that an essential next step is to establish a minimum base offense level, or "floor" for these cases. Establishing a floor will reflect the seriousness of the offense and is consistent with both Congressional intent and the general framework of the guidelines. We submit that a floor of an offense level 14 is appropriate as it is commensurate with the other existing SOC's for which a "floor" has been established and will assure that those convicted of disaster fraud likely will receive an appropriate sentence involving some term of incarceration.² The Department's experience in prosecuting these cases demonstrates that sentences in disaster-fraud prosecutions vary widely, not only in simple, single-application fraud cases but also in cases involving substantial and sophisticated schemes. For example, because sentences have been based upon the fraud table in section 2B1.1(b)(1), first-time offenders generally have been sentenced to probation and fined an amount equivalent to the disaster assistance funds that they fraudulently obtained, even though they may be part of a larger scheme that involves multiple claims for relatively small amounts from a number of false claimants. These probationary sentences do not adequately reflect

¹ For example, many of these offenders commit frauds involving less than \$10,000 of loss and would have a total offense level of 11 under the current guideline. Thus, only in those cases where the "loss" exceeds \$10,000 would some period of imprisonment be recommended.

² Section 2B1.1 provides for the following "floors": single acts of fraud committed during bankruptcy proceedings or involving financial assistance for certain student loans are set a minimum level of 10; if a substantial part of the fraudulent scheme was committed outside of the United States the minimum level is 12; and if the fraud involved an organized scheme to steal vehicles or their parts or goods from a cargo shipment the minimum offense level is 14. Certainly stealing emergency aide to those who are already suffering is at least as serious, if not more, than these offenses. Indeed, one could argue that the concerns expressed in section 2B1.1(b)(13)(B), which assign a floor of 24 for offenses that jeopardize the financial soundness or solvency of an organization, are similar to those noted by Congress in passing the "Emergency and Disaster Assistance Fraud Penalty Enhancement Act of 2007."

the harm caused by these offenses, do not achieve specific or general deterrence and are not consistent with Congress' intent to treat these offense seriously.

These cases are different from other types of government benefit-related fraud, such as unlawfully obtaining social security benefits or welfare fraud. These other fraud offenses are not triggered by a catastrophic event that requires the quick disbursement of funds and services and without some of the typical safeguards. In order to be effective in times of disaster, the aide delivery system must be immediate and, thus, must rely on the honest representations of the applicant. Those that use these emergency situations for their own personal profit commit a far more serious offense than those who try to exploit the typical delivery systems, which generally have well-established verification procedures in place and do not require rapid response and disbursement. Congress recognized these differences by increasing the maximum penalty to 30 years, far higher than the maximum for those statutes generally used to prosecute social security or welfare fraud.³ Because of the nature of the triggering events, these frauds receive much greater public scrutiny and therefore minimal sentences have two deleterious effects. First, they discourage contributors who see that donations are being wasted and that those who undeservedly obtained the funds are receiving little punishment. Second, the current relatively light punishment imposed for disaster fraud encourages the belief that the potential benefits from such fraud far outweigh any possible punishment.

During the hearing, some expressed concern as to whether offenders who may also have been victims of the major disaster or emergency should be treated differently than individuals were not victims. While the suggestion to create a specific departure for "victims" of disaster fraud may have some appeal, we believe the identification of "victims" and the interrelationship between the fraud and "victimization" is, in reality, extremely complex and not susceptible to such generalizations. By definition, those offenders subject to this guideline are not mere victims, but instead have been found criminally liable for defrauding a benefit organization in connection with a declared disaster. The following are some examples of recent cases that have been prosecuted that some may deem to be "victims," yet the offenders were involved in substantial frauds that might well have been even greater but for their being caught.

- *United States v. Thalisha Davis*, CR-07-171-FJP, (M.D. La.): Davis was an evacuee from New Orleans who received over \$19,000 from the Federal Emergency Management Administration (FEMA) on her first disaster assistance application filed in her own name. Davis then filed two additional applications in the name of "Thalisha Smith," using two social security numbers assigned to other individuals. She admitted in Court that she fabricated the Social Security numbers used in the

³ See generally 18 U.S.C. § 1001(False Statements) (establishing a five year maximum); § 1028 (Identification Fraud)(establishing a 15 year maximum); § 1029(Access Device Fraud) (establishing a 10 and 15 year maximum); § 1341(Mail Fraud not related to a major disaster) (establishing a 20 year maximum); and §1343(Wire Fraud not related to a major disaster) (establishing a 20 year maximum).

applications without knowing to whom the numbers were assigned. Davis obtained over \$14,000 on the second application, and was set to receive approximately the same amount on her third application, but FEMA discovered the fraud prior and cancelled the checks before they were cashed. Ms. Davis was also charged with and pled guilty to fraudulently obtaining Disaster Unemployment Assistance (DUA) by falsely reporting that she lost her job because of Hurricane Katrina. Ms. Davis awaits sentencing on these charges.

- *United States v. Edward Good*, H-06-47, (S.D. Tx.): Edward Good was an evacuee from New Orleans who relocated to Conroe, Texas. Through the internet, he filed a legitimate claim with the Louisiana Department of Labor for disaster unemployment assistance. Good admitted at his plea hearing that he realized from this first application that it would not be difficult to submit other applications through the internet. He then purchased (using money or drugs) names and social security numbers from Conroe-area residents which he then used to file DUA claims, listing New Orleans employers of which Good was aware. These individuals were not evacuees and had not worked in Louisiana prior to Katrina. At sentencing, the district court determined that Good filed approximately 70 fraudulent DUA applications, had the debit cards sent to his Conroe hotel room, and received more than \$120,000 in fraudulent funds. He was sentenced to 27 months imprisonment.
- *United States v. Bobby Hammond*, H-07-116, (S.D. Tx.): Hammond was an evacuee from New Orleans who relocated to Houston. He filed a legitimate claim for DUA. The evidence at Hammond's trial established that he then filed a second claim for DUA using another's social security number. The DUA program requires a weekly call to verify continued eligibility in order to receive the weekly \$98 benefit on the debit card. The government put forth evidence at trial showing that each week Hammond called to verify eligibility for both cards. To access the second card, each week he had to enter the false social security number used to obtain that card in the first place. The jury convicted Hammond of wire fraud and aggravated identity theft. Hammond is pending sentencing.
- *United States v. Travis Frank and Regina Dewey*, H-07-135, (S.D. Tx.): Frank and Dewey evacuated from the New Orleans area to Houston. Frank filed a claim for Katrina benefits, listing his primary residence of Reserve, Louisiana. FEMA denied this application. According to the agreed factual proffer at the plea hearing in this case, Frank then filed a second application, fraudulently listing a primary residence in New Orleans. FEMA asked for additional information to support his claim of New Orleans residency. Frank admitted at the plea hearing that he created a fraudulent lease and had his girlfriend Dewey forge the signature of a supposed landlord at the address. Dewey admitted that she also wrote a letter, which was faxed to FEMA, supposedly from the landlord falsely stating that Frank had lived at the New Orleans address. FEMA paid \$12,000 after receiving these fraudulent

address verifications. Frank and Dewey split the money. The district court sentenced Frank to ten months imprisonment and Dewey to a term of time served, which was approximately two months.

While in each one of the cases the defendant might qualify as a "victim," we do not believe that a downward departure would be warranted given the amount and/or degree of sophistication in carrying out the fraud. Nevertheless, should the Commission determine that an offender's "victim" status should be given some consideration, rather than a downward departure, we suggest including an application note indicating that the minimum base offense level should not apply if the defendant was legitimately entitled to some portion of the funds and the funds illegally received were only an extension or overpayment of that which he obtained lawfully. The application note should place the burden on the defendant to establish that he was legally entitled to the initial disbursements and should exclude those who (1) fraudulently obtained or sought to obtain \$5,000 or more in benefits and (2) submitted multiple claims to a single agency or submitted claims to multiple agencies.

Finally the Commission sought comment on "whether the proposed specific offense characteristic should include language expanding the scope of the enhancement to cover fraud or theft involving any benefit authorized, transported, transmitted, transferred, disbursed, or paid in connection with 'any procurement of property or services related to any emergency or major disaster declaration as a prime contractor with the United States or as a subcontractor or supplier on a contract in which there is a prime contract with the United States.'" We believe that it should. The same type of emergencies that necessitate the quick disbursement of funds to individuals who are the victims of a major catastrophe are also present in the contracting process. Due to the same immediate need for services, the contracting process often takes place with little, if any, vetting. Basic services such as gasoline, electricity generators, housing, food, water, must all be supplied, often in large amounts and within hours of the triggering event. As Section 1040 recognizes, these services are desperately needed, yet are susceptible to fraud because of the chaos surrounding the disaster and should be protected by the deterrent effect of increased punishment.⁴

2. Honest Leadership and Open Government Act of 2007

This proposed amendment implements the Honest Leadership and Open Government Act of 2007, Pub. L. 110-81 (the "Act") by referencing the new offenses under 18 U.S.C. § 227 to section 2C1.1 (Offering, Giving, Soliciting, or Receiving a Bribe; Extortion Under Color of Official Right; Fraud Involving the Deprivation of the Intangible Right to Honest Services of Public Officials; Conspiracy to Defraud by Interference with Governmental Functions).

We support this amendment.

⁴ Some have questioned the inclusion of administrative costs in Application Note 3(A)(v)(IV). The definition used here is nearly identical to that included in Application Note 3(A)(v)(II) (Procurement Fraud Cases) and we believe it is appropriate.

3. Miscellaneous Food and Drug Offenses

The Commission has proposed amending the guidelines to include penalties for offenses involving the illegal distribution of hGH and to increase penalties for certain violations of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 301 et seq.) (the "FDCA") and the Prescription Drug Marketing Act of 1987 (the "PDMA"). We support the proposed changes.

These two areas have been the subject of a longstanding concern to the Food and Drug Administration, as was most recently outlined in the testimonies of William McConagha, Assistant Commissioner for Accountability and Integrity; Robert Perlstein, M.D., Medical Officer, Center for Drug Evaluation and Research; and Special Agent Alex Davis, Office of Criminal Investigations. Their testimony and the other available materials establish a firm basis for treating hGH in the same manner as anabolic steroids. Additionally, hGH should be included in SOC 2D1.1(b)(6) and should also be added to SOC 2D1.1(b)(8).

With regard to the other specific issues for comment, we agree with the FDA that the relevant measurement should be of a mixture or substance containing hGH as this is the most practical test not requiring time consuming measurements of purity. The equivalency conversion should use the same methodology that was used in establishing the anabolic steroids based in part on the amount required by a user for "one enhancement cycle." The maximum base offense level of 20 should also apply to hGH with the issue of whether to raise or eliminate that cap to be considered in a future amendment cycle.

With regard to FDCA offenses, section 2N2.1 presently treats both first and subsequent violators of the FDCA the same even though a first offense is only a misdemeanor while a second conviction increases the maximum sentence to three years. We believe the addition of an SOC directed specifically to repeat violations of 21 U.S.C. § 331 would address this problem. An increase of seven levels would be appropriate and would result in a Zone C sentence for someone who pleaded guilty and received a reduction under section 3E1.1(a). We support the amendment to Application Note 3(A) calling for an upward departure if the "offense created a substantial risk of bodily injury" in addition to death or actual injury.

With regard to PDMA offenses, the base offense level of six in section 2N2.1 does not reflect the seriousness of certain offenses that carry a 10-year maximum penalty. We support a new base offense level for those specific offenses and suggest that it be set at 13 so as to parallel the sentence imposed for a second violation of the FDCA. The amended Application Note 3(A) should apply to these cases as well.

4. Animal Fighting Prohibition Enforcement Act of 2007

This proposed amendment results from Congress' decision to increase the maximum penalties for animal fighting from a six-month misdemeanor to a three-year felony. We agree with

the proposal to include this as an offense under section 2E3.1 and that it should have a separate BOL. The BOL should be 10 rather than 8. At a BOL of 10 even an organizer under section 3B1.1(c) with a criminal history I would be eligible for a Zone B sentence of 6 to 12 months after a guilty plea; in contrast, at a BOL of 8, the range would be 0 to 6 months.

We also agree with the inclusion of Application Note 2 suggesting that an upward departure may be warranted if the offense involved extreme cruelty to the animal. We have two additional suggestions. First, in Application Note 1, the Commission should consider including the definition of "Animal Fighting" in the guideline rather than simply including a statutory reference. While such a reference may make sense for title 18 violations, many practitioners do not have easy access to provisions of Title 7. Second, there should be an SOC directing a two-level increase if a firearm or other weapon was possessed in conjunction with the animal fighting enterprise. This enhancement is common in other guideline provisions. See Sections 2A4.1(b)(3), 2B2.1(b)(4), 2B5.1(b)(4), 2D1.1(b)(1), 2E2.1(b)(1), and 2L1.1(b)(5)(C). The guidelines should differentiate between those offenses where firearms are used to further the enterprise and those that do not and provide increased punishment for this increased risk.

5. Technical Amendment

This six-part technical amendment would make several changes to the guidelines to correct technical errors or to include conforming language. We have no objection to these changes.

6. Criminal History

The proposal would clarify the definition of arrest to include "an attempted service of an arrest warrant where the defendant escapes the arrest or the service of the arrest warrant". We support this change.

7. Immigration

The Commission undoubtedly has had a difficult task responding to the frequent changes to 8 U.S.C. § 1326 the statute that either increased the penalties or expanded the definition of "aggravated felony" or both. Not surprisingly, courts have rendered often conflicting opinions on what offenses qualify under various categories while also placing restrictions on the manner of proof, thus limiting the ability to use prior convictions anticipated by the statutes and guidelines as the basis for increased sentences. Given that historical context to the options proposed, we believe that another attempt at defining terms will not alleviate the problems.

The Commission is aware of our strong support for a version of Option Three. Under this approach, the Guideline calculation is driven primarily by the length of sentence imposed for prior

convictions. Although state sentencing regimes are not entirely uniform, the length of sentence imposed provides a far more objective and readily-determined basis for an increased offense level under Section 2L1.2 than does the current categorical approach, which is governed entirely by varying practices in charging and record-keeping among the 50 states and thousands of counties and parishes throughout the United States. At the same time, for very serious offenses, namely a prior felony conviction for murder, rape, kidnapping, a human trafficking offense, a child pornography offense, or an offense of child sexual abuse, it would keep the present categorical approach. In our experience, the litigation surrounding these offenses has not proven to be as problematic as with other offenses current listed in section 2L1.2(b).

We believe length of sentence has been proven to be an appropriate indicator of the seriousness of an offender's prior record. The present criminal history categories in the Guidelines are largely based on sentence length and extensive study by the Commission has shown a direct relationship between recidivism and these same criminal history categories. While some have expressed concern with the disparate way sentences are imposed from one jurisdiction to another, this problem already exist in the guidelines because sections 2L1.2(b)(1)(A)(i) and (B) both are currently keyed to the length of sentence imposed.

Option Three, however, could be improved by including certain provisions from the other proposed options. Option Two includes at Application Note 4 departure considerations in those cases where the defendant has been removed from the United States multiple times or where the Court finds that the resulting offense level "substantially overstates or understates" the seriousness of the prior conviction. The latter consideration parallels the present language of Section 4A1.3 (Criminal History) and would provide judges with the flexibility to address the concern that sentences for illegal aliens sometimes understate the seriousness of the underlying offense because the local court takes into account the fact that the illegal alien will be deported upon completion of the sentence. We also suggest including the definition of "forcible sex offense" proposed in sub-option A of Option One for the definition of "Crime of Violence."

With regard to Option One, the proposed change to the definition of a "drug trafficking offense" included in Sub-option A and the proposed inclusion of a definition for "forcible sex offense" will correct clear appellate errors in interpreting the intent of the Commission regarding the scope of these terms and we therefore support those specific amendments. These changes, however, will have little effect on the widely-expressed concerns regarding the general difficulty in applying section 2L1.2 and ultimately will not alleviate the substantial amount of litigation resulting from the categorical approach.

Adoption of sub-option 1(A) may alleviate some litigation burden. By including "an offense that, by its nature, involves a substantial risk that physical force against the person of another will be used in the course of committing the offense," this option eliminates the need to parse through the multitude of comprehensive statutes that contain alternative elements involving both the use and/or substantial risk of use of physical force. Because the proposed change would

bring the guideline in line with the current definition of crime of violence found at 18 U.S.C. § 16, courts would be able to rely on the years of precedent already established.

We also strongly support the proposed Departure Consideration 7(A) which suggests an upward departure for prior drug possession convictions where the amount of the drugs possessed exceeds an amount for personal use. Rather than merely including this consideration as a potential departure basis, we propose that drug possession convictions involving large amounts of drugs be included in the amended definition of a drug trafficking offense. The failure to include prior felony convictions of large amounts of drugs leads to disparity in treatment of like defendants simply because of the vagaries of local statutes and charging practices. For example, under the current guideline, a defendant who was previously convicted of possessing with intent to distribute one gram of crack will have his base offense level increase by at least 12 levels, and perhaps 16, depending upon the length of sentence imposed. On the other hand, if a defendant had previously been prosecuted in a jurisdiction which uses a felony possession offense as their primary statute for drug prosecutions, he would receive at most a four-level increase even if he possessed five kilograms of cocaine. If both defendants were a criminal history II and had previously received a sentence imposed of greater than 13 months, then under current section 2L1.2, the first defendant would have get a sentence of 57-71 months (before acceptance) while the five kilogram defendant would be subject to a maximum sentence of 12-18 months. This disparity is hard to explain and can be corrected by including the large quantity drug possession cases in the definition of "drug trafficking offense."

The Commission's consideration of these options must, however, be informed by an additional factor that has already impacted the fairness, and will increasingly do so in the future, of current section 2L1.2(b) or the application of Option One. That factor is the disappearance of the complete records necessary to make the factual and legal determinations required to apply the SOC's. When presented with a request for records some local courts now are providing only an abstract of a conviction record. That abstract usually includes the defendant's name, some other identifiers, a description of the offense, statute of conviction, the date of sentence, the actual sentence imposed. The information about the offense characteristics and statutory reference is often generic rather than specific, leading to an inability to identify the specific charge that would serve as the predicate for the SOC's.⁵ In some instances, the necessary underlying information is unavailable due to a court's practice of destroying records after a period of time. As a result, application of the enhancements under existing section 2L1.2 or under Option One will depend upon how the local jurisdiction keeps and reports its records. Adoption of Option Three helps avoid that disparate effect.

⁵ Using the United States Code as an example, an abstract might state that the defendant had been convicted of "tampering with a witness, victim or an informant" in violation of 18 U.S.C. § 1512. A court, looking at that statute, would find violent and non-violent offenses, felonies and misdemeanors. It would be necessary to find additional information (information which may no longer be available) before the court could determine whether one of the SOC's applied to that conviction.

There has been some question as to whether a "sentenced-based" guideline such as that proposed in Option Three would avoid many of the problems resulting from the increasing reliance upon sentencing abstracts. While the Ninth Circuit has limited the use of an abstract to establish the specific type of offense of conviction, it has accepted their use for proving the length of sentence. In *United States v. Sandoval-Sandoval*, 487 F.3d 1278, 1280 (9th Cir. 2007) the Court addressed this issue:

Defendant challenges this use of the abstract of judgment, asserting that our decision in *United States v. Navidad-Marcos*, 367 F.3d 903 (9th Cir. 2004), prohibits district courts from relying on abstracts of judgment. That broad proposition is incorrect. In *Navidad-Marcos*, we held that a district court may not rely on an abstract of judgment to determine the *nature* of a prior conviction for purposes of analysis under *Taylor v. United States*, 495 U.S. 575 (1990). We held that the documents contain insufficient information for that purpose. We did not hold, as Defendant contends, that abstracts of judgment are categorically unreliable. Indeed, recently, we permitted reliance on an abstract of judgment, in combination with the charging document, for the purpose of determining whether a defendant had a qualifying conviction under U.S.S.G. § 2L1.2(b)(1)(A). *United States v. Valle-Montalbo*, 474 F.3d 1197, 1201-02 (9th Cir. 2007).

Here, as in *Valle-Montalbo*, the district court relied on the abstract of judgment to determine a discrete fact regarding Defendant's prior conviction, namely, the length of sentence imposed. *People v. Mitchell*, 26 Cal.4th 181, 109 Cal.Rptr.2d 303, 26 P.3d 1040, 1042-43 (2001). The document unequivocally contained the information needed. This was a permissible use of the abstract of judgment. Therefore, the sentence is not erroneous for the reason that Defendant argues.

Thus, while abstracts have been problematic in developing an adequate basis for the application of certain SOC's under current section 2L1.2(b) or under Option One, they are accepted as adequate proof of length of sentence imposed.

8. Court Security Improvement Act of 2007

On January 7, 2008, the President signed into law *The Court Security Act of 2007*, Pub L. 110-177. Among its many provisions it created two new offenses: 18 U.S.C. § 1521, retaliating against a federal judge or federal law enforcement officer by false claim or slander of title, which is punishable by up to 10 years in prison, and 18 U.S.C. § 119, protection of individuals performing certain official duties, which is punishable by up to five years in prison.

We submit that the appropriate guideline for the new offenses of retaliation by filing a false lien should be section 2A6.1 (Threatening or Harassing Communications; Hoaxes).⁶ Under section 2A6.1 the base offense level for these offenses would be 12. In addition, we suggest that the SOC's contained in section 2A6.1(b)(2)-(4) should be amended so as to apply to the filing of multiple false liens, or filings that violate a specific court prohibition, or are so voluminous and disruptive as to cause a substantial amount of effort to remove them. Further we believe it would avoid substantial litigation if an Application Note was added to assure the application of section 3A1.2(a) and (b).

As to the new offense at 18 U.S.C. § 119, making public restricted personal information with the intent that "the information will be used, to threaten, intimidate, or incite or facilitate the commission of a crime of violence against that covered person or a member of that person's immediate family" we believe that the appropriate guideline is section 2H3.1, which presently includes, among other things, the "Disclosure of Certain Private Protected Information." The base offense level under section 2H3.1 is nine and we recommend a new SOC calling for a six-level increase if the defendant is convicted for a violation of 18 U.S.C. § 119. We also suggest that there be a second SOC that would call for an additional two-level increase if the restricted information was made available by use of the internet since use of the electronic medium would facilitate its widespread dissemination and make the likelihood of someone using the information for the desired purpose all the more likely. With these two SOC's the guideline range for a defendant with Criminal History VI would be 51-63 months, *i.e.*, at the maximum statutory sentence.

Our final comment pertains to what we believe is the unreasonably low maximum sentence for 18 U.S.C. § 119, an offense that involves taking significant steps in an attempt to have someone commit a crime of violence against a protected person. The maximum sentence should be substantially more than five years. Section 994(r) of Title 28 states:

The Commission, not later than two years after the initial set of sentencing guidelines promulgated under subsection (a) goes into effect, **and thereafter whenever it finds it**

⁶ Alternative suggestions have been to include this new statute in section 2J1.2 (Obstruction of Justice) or section 2B1.1 (Offenses Involving Fraud or Deceit). As to section 2J1.2, while the offense may appear to be that of an obstruction of justice, our experience is that in many instance the filings have nothing to do with an intent to influence any particular case but instead are simply a tool used to harass certain specified individuals. In fact, corrections officers in the federal penitentiaries where the defendants are serving previously imposed sentences frequently are the target of these harassing actions. While the offense does involve fraud and deceit, there is often no actual monetary loss and the gravamen of the offense is harassment, not the deceit. If section 2B1.1 were to apply, the sentencing courts would be required to look at the expenditures made for "clearing title" and the seriousness of the offense could well be determined by the wealth of the victim and the cost of the property subject to the lien. We do not believe that is a desirable methodology for determining length of sentence.

advisable, shall recommend to the Congress that it raise or lower the grades, or otherwise modify the maximum penalties, of those offenses for which such an adjustment appears appropriate.

(emphasis added). When forwarding the proposed amendments to Congress, the Commission should include a recommendation that the maximum sentence for this offense be increased.

9. Rules of Practice and Procedure

The Commission has proposed amending *Commission's Rules of Practice and Procedure* Rule 4.1 - Promulgation of Amendments by deleting the present requirement that it "shall decide whether to make the amendment retroactive at the same meeting at which it decides to promulgate the amendment." Rather than remove the linkage between the decision to amend a specific guideline and making that decision apply retroactively, the Commission should look to amendments that would further strengthen that requirement and assure that there is an opportunity for informed Congressional review.

While we recognize that presently there is no statutory requirement that the Commission give Congress an opportunity to review a decision to give an amendment retroactive effect, the Commission acknowledged the propriety of this critical review function when it wrote the current rule in 1997. Given the recent criticism of the Commission's decision to apply the crack amendments retroactively and the specific complaints from members of Congress that postponement of the decision until after November 1st precluded meaningful Congressional review, we believe this proposed change to the Commission's rule moves in the wrong direction.

In enacting this rule in 1997, the Commission recognized the interrelationship of the decision to amend a guideline so that the resulting sentences would be reduced and the decision as to whether or not that reduction should apply retroactively. Obviously, the second decision cannot occur without the first. Perhaps less apparent, but just as important, is the impact that the decision to apply an amendment retroactively could and should have on the Congressional review of the amendment itself. In enacting 28 U.S.C. 994(p), Congress clearly felt that this review should not be perfunctory and thus required at least a six-month delay before any amendment to the guidelines could go into effect.⁷ While Congress did not address review of

⁷ Title 28, United States Code, Section 994(p) states:

The Commission, at or after the beginning of a regular session of Congress, but not later than the first day of May, may promulgate under subsection (a) of this section and submit to Congress amendments to the guidelines and modifications to previously submitted amendments that have not taken effect, including modifications to the effective dates of such amendments. Such an amendment or modification shall be accompanied by a statement of the reasons therefor and shall take effect on a date specified by the

retroactivity decisions, the Commission recognized that the two decisions should not be bifurcated. Thus, the Commission included in its rules the requirement that the decision on retroactivity be made at the same time as the decision on the amendment.

Some have expressed concern that it may be impractical in some circumstances to begin the retroactivity impact analysis and request public comment on the retroactive application of an amendment prior to a vote on the amendment at issue. The solution, however, is not to preclude Congressional review; instead, the Commission ought to seek a statutory change that would permit both. This could be accomplished in a number of ways. Section 994(p) could be amended so that it also applies to the general policy statements, thus making any change to section 1B1.10 subject to the current six-month Congressional review. Alternatively, Congress could add an entirely new subsection that would "delink" the retroactivity decision from the deadlines of § 994(p) and instead allow the proposed amendment to section 1B1.10 to be submitted to Congress at any time with a delay of six months before it could go into effect. We suggest combining these two solutions by amending § 994(p) so that after the Commission submitted to Congress a proposed amendment it would have five months to decide whether it wants to make the amendment retroactive. If, in that period, the Commission decided it did not want to apply the amendment retroactively, it would do nothing and the provisions of current § 994(p) would apply. If, on the other hand, the Commission decided to apply the amendment retroactively, it would inform Congress and by statute both decisions would be subject to an additional six-month review period. Finally, if after five months, the Commission was still unable to make a decision on retroactivity, it could so inform Congress and the amendment would be withdrawn. It then could be resubmitted any time after the start of the next session of Congress.

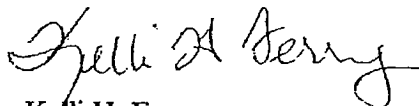
We believe that this final alternative would permit Congress to exercise its right to review the proposed amendment and all of its potential ramifications. Depending upon the situation, Congress may decide that it would not agree to a reduction if it meant it would apply retroactively. Congress could then decide whether to reject the amendment entirely or, alternatively, to delete the corresponding amendment to section 1B1.10. On the other hand, if Congress had the Commission's impact analysis, it could decide to allow the entire amendment to go into effect. Regardless of Congress' ultimate decision, this process would assure that the Commission's critical decisions would be subject to the Congressional oversight that was clearly intended when the guideline procedures were originally enacted.

Commission, which shall be no earlier than 180 days after being so submitted and no later than the first day of November of the calendar year in which the amendment or modification is submitted, except to the extent that the effective date is revised or the amendment is otherwise modified or disapproved by Act of Congress.

* * * * *

Thank you for the opportunity to provide the Commission with our views, comments, and suggestions. We look forward to our continuing work with the Commission in the important area of sentencing guidelines and policy.

Sincerely,

A handwritten signature in cursive script, reading "Kelli H. Ferry".

Kelli H. Ferry

Counselor to the Assistant Attorney General

COMMENT BY THE US FOOD AND DRUG ADMINISTRATION

On January 28, 2008, the United States Sentencing Commission (the Commission) proposed to amend the United States Sentencing Guidelines to address several offenses set forth in the Federal Food, Drug, and Cosmetic Act (FDCA). Specifically, the Commission requested comment on its proposal to sentence illicit human growth hormone (hGH) distribution under § 2D1.1 of the guidelines, as well as on several specific questions related to hGH sentencing. In addition, the Commission requested comment regarding the sentencing of Prescription Drug Marketing Act (PDMA) violations and other FDCA violations currently sentenced under § 2N2.1. FDA's recommendations concerning these areas of proposed amendment follow. First, the comment addresses the issues related to illicit distribution of hGH under 21 U.S.C. § 333(e). Second, the comment provides information and recommendations for certain PDMA violations. Third and finally, the comment responds to the Commission's request for comments regarding the adequacy of § 2N2.1 generally and the Commission's proposed amendments in particular.

I. HUMAN GROWTH HORMONE

The FDCA prohibits the knowing distribution, or possession with the intent to distribute, hGH for any use not authorized by FDA. See 21 U.S.C. § 333(e). As the Commission is aware, there currently is not a sentencing guideline to cover these hGH offenses. See USSG § 2N2.1, comment (n.4). The Commission has proposed adding "references to §§ 2D1.1 and 2D1.2 in Appendix A for violations of 21 U.S.C. §§ 333(e)(1) and (e)(2), respectively; amend[ing] the specific offense characteristics at § 2D1.1(b)(6) to include hGH offenses; and delet[ing] language in the commentary to § 2N2.1 stating that the Commission has not established a guideline for hGH offenses." 73 Fed. Reg. 4931, 4934 (Jan. 28, 2008). The Commission has also requested comment in response to several issues related to its proposal, including: how hGH should be quantified under § 2D1.1; what quantity of hGH should be used to determine a "unit" for purposes of calculating the base offense level; whether and to what extent should a maximum base offense level apply; and whether certain enhancements should be expanded to include certain hGH offenses, as well as whether any modifications should be made to an existing Application Note.

The United States Food and Drug Administration (FDA), which is the agency charged with the responsibility of investigating criminal violations of the FDCA, believes that a sentencing guideline for hGH offenses is necessary, and it is submitting this comment in support of the Commission's proposal. As discussed below, FDA recommends that the Commission establish that: (a) hGH be quantified under § 2D1.1 by measuring the total amount of powder containing hGH; (b) ten milligrams (10 mg) of the weight of the powder containing hGH be equated to one "unit" for purposes of calculating the base offense level; (c) a maximum base offense level of twenty (20) should apply for now; (d) the scope of enhancements be expanded to cover the distribution of a masking agent for hGH testing and the illegal distribution of hGH to an athlete; and (e) the relevant application note be modified to provide that the adjustment for abuse of trust applies to a coach who influences an athlete to use hGH.

A. A Sentencing Guideline Is Needed For hGH Offenses

FDA's ability to pursue enforcement actions for hGH offenses is currently hampered by the uncertainty that results from the current lack of a sentencing guideline. Prosecutors, probation officers, and others have expressed confusion about how to calculate the guidelines for hGH offenses. Because there currently is substantial interpretive room in selecting an analogous guideline, as courts are directed to do by § 1B1.2(a) when no specific guideline is available, probation officers and courts may refer to any number of guidelines to calculate hGH sentences, including § 2N2.1 (Food and Drug Offenses), § 2B1.1 (Theft, Property Destruction, and Fraud), § 2D1.1 (Drug Offenses), or § 2X5.1 (which states that courts should make use of the criteria in 18 U.S.C. § 3553 when no sufficiently analogous guideline is available).¹ These differing approaches may result in widely varying sentences, which can result in perceived unfairness to defendants and in diminished deterrence. Defendants may face substantial uncertainty estimating their likely sentencing exposure, and a defendant in one jurisdiction with identical conduct might find himself sentenced more harshly than a defendant in another jurisdiction that uses a different approach to sentencing hGH violations. In addition, as the Commission is aware, uncertainty also diminishes deterrence when the criminally-minded underestimate the consequences of their conduct. The same uncertainty exists for the probation officers and judges charged with calculating and applying sentencing criteria. FDA believes that the Commission's proposed guideline would be a positive step in resolving the uncertainty that currently exists for sentencing violations of 21 U.S.C. § 333(e).

B. FDA Supports The Commission's Proposal

FDA supports the Commission's proposal to sentence illicit hGH distribution under §2D1.1, which currently addresses certain controlled substances offenses. Although hGH is not a controlled substance, its well-known adverse effects, ease of illegal distribution, and potential for abuse -- especially in conjunction with anabolic steroids -- establish a logical nexus for sentencing hGH under § 2D1.1.

As discussed in detail in the previously submitted written statement of Dr. Robert Perlstein, hGH is a 191-amino acid polypeptide hormone secreted by the anterior pituitary gland. It has important metabolic effects, including stimulation of protein synthesis and cellular uptake of amino acids, and stimulates normal growth in children. The approved indications in adults include biochemically-documented severe growth hormone deficiency due to defined organic diseases (hereafter, referred to as "severe growth hormone deficiency"), AIDS wasting, and short bowel syndrome.

All hGH products are prescription drugs because, due to the potential for well-known adverse effects, they are not safe for use except under the supervision of a practitioner licensed by law to administer such products. See 21 U.S.C. § 353(b)(1). The use of hGH is frequently associated with fluid retention, which can cause edema, arthralgia (joint pain), myalgia (muscle

¹ Also, as noted in the previous oral testimony of FDA Special Agent Alex Davis, hGH is often distributed with anabolic steroids. Because anabolic steroids have defined sentencing guidelines, some prosecutors focus on the controlled substances offenses and ignore the hGH offenses. Moreover, even when prosecutors charge both the hGH and controlled substances offenses, the hGH charges may be disregarded during sentencing.

pain), and carpal tunnel syndrome. It can also exacerbate pre-existing hypertension (high blood pressure) and congestive heart failure. The risk of incurring the side effects associated with fluid retention increases with age. hGH also has anti-insulin, diabetogenic effects that may contribute to the development of diabetes mellitus, especially in those predisposed to this disease.

As FDA Special Agent Alex Davis discussed in his written testimony, the illegal distribution of hGH appears to be increasing, which can be attributed to the perceived effects of hGH on athletic performance and on stopping or slowing the aging process,² coupled with the relatively low cost of black-market hGH and the ease of obtaining it without a prescription.

Most of the hGH that is promoted to stop or slow the aging process or to increase athletic performance is unapproved product that is primarily manufactured by foreign drug sources and imported into the United States. Internet websites and discussion boards have made it very easy for anyone to order hGH that originates from one of the numerous foreign sources and have it delivered to his or her door. The hGH purchased from a website or internet discussion board is almost always significantly cheaper than FDA-approved hGH. Depending on the brand offered for sale, 100 International Units (IUs) of black-market hGH can be purchased for \$200 - \$700. However, 100 IUs of FDA-approved hGH that is properly dispensed by a pharmacist costs approximately \$2000, which is more than twice as much as the most expensive black-market price. As explained infra Section I.C.2., those using hGH for anti-aging will use amounts near to or greater than amounts for adults with severe growth hormone deficiency, and those using hGH to increase athletic performance will typically use amounts far in excess of the amounts for adults with severe growth hormone deficiency.

Anabolic steroids, which are Schedule III controlled substances, are distributed in much the same manner as hGH -- that is, they typically are imported from a foreign source and sold over the internet, either through a website or a bodybuilding discussion board. Because of the perception that hGH increases lean muscle mass, hGH is often used in conjunction with anabolic steroids and a bodybuilding routine to increase athletic performance. Therefore, those who are distributing steroids are very often the same individuals who are distributing hGH, and many of the websites and internet discussion boards that offer hGH for sale will also offer anabolic steroids for sale.

Likely because hGH has a potential for abuse in conjunction with anabolic steroids and, as discussed infra Section I.C.2., a potential for harm that is equal to that of anabolic steroids, 21 U.S.C. § 333(e) is more closely analogous to a provision of the Controlled Substances Act ("CSA") than to a typical drug offense under the FDCA. For instance, although most food and drug offenses under the FDCA carry a maximum penalty of three years in prison, Congress established greater penalties for the unlawful distribution of hGH. Cf. 21 U.S.C. § 333(a) and (e). The penalties for hGH distribution are similar to the penalties for Schedule III controlled

² See, e.g., Hau Liu, MD, MBA, MPH, et al., Systematic Review: The Safety and Efficacy of Growth Hormone in the Healthy Elderly, 146 ANNALS OF INTERNAL MED., 104 (Jan. 16, 2007) (concluding that, based on the evidence, growth hormone cannot be recommended as an antiaging therapy); Hau Liu, MD, MBA, MPH, et al., Systematic Review: The Effects of Growth Hormone on Athletic Performance, 148 ANNALS OF INTERNAL MED., to be published May 20, 2008, available at <http://www.annals.org/cgi/content/full/0000605-200805200-00215v1> (concluding that the limited available evidence suggests that growth hormone increases lean body mass, but it may not improve strength, may worsen exercise capacity, and may increase adverse events).

substances, such as anabolic steroids, in that whoever violates 21 U.S.C. § 333(e) "is guilty of an offense punishable by not more than 5 years in prison," and whoever violates said provision "and such offense involves an individual under 18 years of age is punishable by not more than 10 years imprisonment" 21 U.S.C. § 333(e)(1) and (2); cf. 21 U.S.C. § 841(b)(1)(D). Also, unlike other violations of the FDCA, a conviction for violating 21 U.S.C. § 333(e), "shall be considered a felony violation of the Controlled Substances Act for the purposes of forfeiture under [the CSA]." 21 U.S.C. § 333(e)(3). Finally, the Drug Enforcement Administration, which is charged with investigating violations of the CSA, is also authorized to investigate hGH offenses. See 21 U.S.C. § 333(e)(5). Because of these similarities, it is reasonable and appropriate to sentence hGH offenses under § 2D1.1.

In fact, the similarities between hGH and Schedule III controlled substances are such that there have been recent efforts by some members of Congress to add hGH to the list of Schedule III controlled substances under the CSA. These efforts, however, should not delay the Commission from establishing a guideline for hGH offenses under the FDCA. Proposed legislation to add hGH to the list of controlled substances has been pending since March 14, 2007, and it is by no means a certainty that Congress will schedule hGH any time soon. See e.g., Controlling the Abuse of Prescriptions Act of 2007, S. 877, 110 Cong. (2007). Also, none of the proposed legislation that has been introduced in Congress to date would repeal 21 U.S.C. § 333(e); therefore, a sentencing guideline for such offenses would be necessary regardless of whether Congress schedules hGH. But even if Congress were to repeal 21 U.S.C. § 333(e) and schedule hGH in the CSA, prosecutors, defendants, and courts would be without a sentencing guideline until at least the next amendment cycle, when the Commission would have another opportunity to establish an hGH guideline. Therefore, FDA does not believe that the Commission should delay establishing a guidelines because regardless of what action, if any, Congress takes, the Commission's proposal would still further Congress' intent for sentencing hGH offenses.

C. FDA's Responses To The Commission's Specific Requests for Comment

As discussed below, FDA recommends that: (1) hGH be quantified under § 2D1.1 using the total weight of powder containing hGH; (2) the appropriate base offense level for hGH offenses be determined using a 1 unit = 10 milligrams of total powder formula; (3) the maximum base offense level for hGH offenses be equivalent to that for anabolic steroids offenses; and (4) enhancements be added for a masking agent and distribution of hGH to an athlete and the relevant application note be amended to address abuse of trust by a coach.

1. Quantifying hGH Under Section 2D1.1

FDA recommends that the Commission use the total weight of hGH powder as the unit of measurement that is equivalent to 1 gm of marijuana. As the Commission is aware, calculation of quantity based on total weight of the substance is the approach used for most substances in Table C of § 2D1.1, including anabolic steroids, and the Supreme Court has approved such an approach. See Chapman v. United States, 500 U.S. 453, 461 (1991) (noting that "Congress adopted a 'market-oriented' approach to punishing drug trafficking, under which the total

quantity of what is distributed, rather than the amount of pure drug involved, is used to determine the length of the sentence.").

Using the total weight of the powder as the unit of measure is reasonable considering that hGH is illegally distributed in powder form. A person wishing to use hGH for an anti-aging or bodybuilding use will usually purchase multiple "kits" of hGH over the internet. Each kit typically consists of several vials containing hGH in the form of a lyophilized (freeze-dried) powder mixed with several excipients (inactive ingredients), such as mannitol, glycine, and phosphate. These excipients are included in the formulated product to help solubilize the hGH, for pH control, and to promote the stability of the hGH once it is in solution. Although hGH must be injected to be metabolized by the body, the vials always contain hGH in the form of a lyophilized powder until they reach the customer because liquid hGH quickly loses potency if it is not refrigerated.

FDA believes that using the total weight of the powder containing the active hGH ingredient will be the most efficient means of measure. To determine whether hGH is present in a particular sample and thus to confirm whether 21 U.S.C. § 333(e) has been violated, FDA's Forensic Chemistry Center (FCC) uses a method (liquid chromatography with mass spectral detection) that requires at least three hours of labor. If FCC were also then required to test for the amount of the active hGH ingredient for sentencing purposes, FCC would need to use a different test (size exclusion chromatography). This additional procedure would require approximately three additional work-hours per unit being tested. Thus, from FDA and FCC's perspective, using total weight as the measure of hGH quantity is significantly less resource and time intensive than the alternative of requiring the government to test hGH samples for quantity of active ingredient. Using the total quantity of hGH powder decreases the testing time literally in half. Because FCC's resources are finite and the demands on their facilities for other types of testing are high, the additional burden of testing for the quantity of active hGH would be significant.

FDA also believes that, while perhaps expedient, the use of the number of hGH vials as the appropriate measure of hGH quantity for guideline purposes would present problems. Equating a number of vials of hGH with a number of "units" would create an incentive for illicit distributors to increase the size of their vials and thereby decrease the number of vials counted for sentencing purposes for the same quantity of hGH. Vial size could easily be changed at any point in the distribution chain. FDA can, with minimal burden, determine the total weight of powder contained in a particular or average vial. Therefore, FDA does not believe that there is any significant benefit to using the number of vials as opposed to the total weight of hGH powder. Rather, FDA believes that total weight of hGH powder can provide a consistent, accurate, and fair measure of the quantity of hGH involved in the offense without significantly increasing the burden on FDA's testing facilities by requiring a determination of the quantity of active ingredient in each sample or vial.

2. Quantities for Purposes of Calculating the Base Offense Level

The Commission has requested comments on the harmfulness of hGH offenses relative to steroids offenses and, based on that comparison, input regarding the appropriate quantity of hGH that should be used to determine a "unit" for purposes of calculating the base offense level.

While FDA considers relative harm between hGH and steroids to be relevant to the determination of the proper quantity of hGH to calculate a base offense level, FDA believes that such a comparison does not tell the entire story. FDA has looked at a number of factors in determining a fair and accurate conversion factor for hGH, including: the typical dosage of hGH for adults with severe growth hormone deficiency compared to the dosages for anti-aging and to enhance athletic performance, the potential harm caused by such dosages, the total amount of powder containing hGH used for such dosages, and the typical amount of powder illicitly distributed. Taken together, FDA recommends that the Commission equate 1 unit to 10 milligrams of total powder of hGH to calculate base offense levels.

As discussed above, FDA has approved several hGH products for three adult indications. However, the majority of hGH lawfully prescribed for adults is for the treatment of severe growth hormone deficiency. Adults who are diagnosed with severe growth hormone deficiency take 5 to 10 micrograms of hGH per kilogram of body weight per day. The well-known adverse effects of hGH can occur at those dosages, and such users of hGH are supervised by medical professionals who carefully titrate the dose and supervise its administration so that its use is both safe and effective. Those using hGH for anti-aging purposes will typically take 0.33 to 1.0 milligrams of hGH active ingredient per day, and those using hGH to increase athletic performance will take 1.3 to 3.3 milligrams of active hGH ingredient per day. (One milligram is equal to 1,000 micrograms). The dosages for anti-aging purposes or to increase athletic performance generally are not connected to body weight. Thus, to get a meaningful comparison of the anti-aging and athletic performance dosages to the dosages for adults with human growth hormone deficiency, the anti-aging and athletic performance dosages must be converted to a dosage per kilogram per day. For the sake of comparison, FDA has chosen a hypothetical 80 kg (176 lbs.) adult.

In an 80 kg (176 lbs.) adult, the dosages for anti-aging are equal to 4 to 12 micrograms per kilogram per day and the dosages for athletic performance are equal to 16 to 41 micrograms per kilogram per day. A comparison of those dosages to the dosages for adults diagnosed with severe growth hormone deficiency shows that those using hGH for anti-aging purposes typically are using amounts that are near to or greater than the typical dosages taken by severely growth-hormone deficient adults and those using hGH to increase athletic performance are taking amounts far in excess of those dosages. These higher doses increase the risk of the well-known adverse effects of hGH at the typical dosages, and the lack of adequate monitoring by a well trained physician enhances these risks.

As discussed by Dr. Robert Perlstein in his statement to the Commission, if excessive amounts of hGH are injected over a prolonged period of time, it may lead to the development of acromegaly (typically the result of an unusual pituitary tumor that secretes hGH in an unregulated, autonomous fashion). Adults with acromegaly have enlarged hands and feet, a

protruding jaw and forehead (so-called acromegalic facies), and often develop enlarged internal organs including the heart (so-called acromegalic cardiomyopathy), hypertension, diabetes mellitus and sleep apnea. If left untreated, patients with acromegaly die prematurely, most often due to cardiovascular disease. It is possible, but not yet proven, that the prolonged use of hGH (either directly or via its mediator/surrogate insulin-like growth factor I [IGF I]) may increase the risk of de novo cancer or the growth rate of preexisting cancer. In this regard, patients with naturally occurring acromegaly have an increased risk of colonic polyps and colon cancer. In the opinion of Dr. Perlstein, the unique adverse effects associated with the inappropriate, inadequately monitored use of hGH, and the unique adverse effects associated with such use of anabolic steroids are potentially equally dangerous to the user.

Very little lyophilized hGH powder is needed to achieve potentially dangerous dosages. Data gathered by FDA's Forensic Chemistry Center (FCC) from over two-hundred seventy five criminal investigations show that, on average, the active hGH ingredient makes up 6.4% of the total weight of the illicit product. Therefore, a person on a typical anti-aging regimen would use 5 to 15 milligrams of total powder per day, and a person taking hGH for athletic performance would typically use 20 to 52 milligrams of total powder per day. Compare those amounts to an 80 kg adult who would use 6 to 12.5 milligrams of total powder to get 5 to 10 micrograms of hGH per kilogram for severe growth hormone deficiency.³

As explained above, the 80 kg adults who are using as little as 6 to 12.5 milligrams of total powder per day for severe growth hormone deficiency (and those under 80 kg use even less), could experience the well-known side effects of hGH even when supervised by a medical professional. A similar rate of side effects is likely to be experienced by adults who use 5 to 15 milligrams of total powder per day for anti-aging without the supervision of a medical professional, and it is reasonable to project that persons using greater amounts for athletic performance will experience more severe adverse effects.

Based on the typical dosages discussed above and the risk of harm related to these dosages, FDA is convinced that its proposed conversion, where 1 unit = 10 milligrams of total powder, is an appropriate ratio. FDA believes that its proposal is consistent with the potential for harm in relation to anabolic steroids and would result in fair and appropriate sentences for hGH offenses. An analysis of several recent investigations into illegal hGH distribution schemes indicates that FDA's proposal, when compared to a 1 unit = 45 milligrams or 1 vial ratio,⁴ would be more effective in stratifying high-level, mid-level, and low-level hGH distributors while also accounting for the potential harm caused by the product. Because there currently is not a sentencing guideline for hGH offenses, it has not been necessary for the government to calculate the amount of hGH involved in most distribution schemes.⁵ However, FDA reviewed the available information from ten investigations since 2005. We believe that this information is

³ These numbers are based on the amount of active ingredient typically contained in the forms of hGH distributed in illicit schemes investigated by FDA. The amount of total powder typically used by an 80 kg. severely growth-hormone deficient adult might differ.

⁴ According to FCC, each vial of illicitly distributed hGH contains approximately forty five (45) milligrams of total powder, on average.

⁵ As discussed supra note 1, when a defendant has been accused of committing a controlled substance offense and hGH offense (which happens often), the hGH offense may ultimately not be charged or, if charged, disregarded during sentencing.

fairly representative of the number of hGH vials that are involved in illegal hGH distribution schemes.⁶ This information and the relevant unit conversions appear in Table 1 below.

Table 1

Vials	Mg of Total hGH Powder ⁷	If 1 Unit = 45 mg or 1 vial (Base Level)	If 1 Unit = 10 mg (Base Level)
100	4500 mg	100 units (6)	450 units (8)
110	4950 mg	110 units (6)	495 units (8)
130	5850 mg	130 units (6)	585 units (8)
200	9000 mg	200 units (6)	900 units (8)
280	12600 mg	280 units (8)	1260 units (10)
355	15975 mg	355 units (8)	1597.5 units (10)
650	29250 mg	650 units (8)	2925 units (12)
900	40500 mg	900 units (8)	4050 units (12)
1001	45045 mg	1001 units (10)	4504.5 units (12)
1150	51750 mg	1150 units (10)	5175 units (14)

These investigations reveal that most of the cases where judicial action was obtained would fall at level 6 or 8 if one vial or 45 milligrams of hGH constituted one "unit" under Table C of § 2D1.1. With a substance as potent as hGH, not only does the culpability differ dramatically between a distributor who sells 4.5 grams (4,500 milligrams) and distributor who sells 40.5 grams (40,500 milligrams), but the public health implications also differ dramatically. Yet, based on the quantities of hGH seen in recent FDA cases, and assuming a conversion rate of 45 milligrams of total powder or at one "vial" per "unit" for sentencing purposes, the individual distributing 4.5 grams would receive a base level of 6 and the individual distributing 40.5 grams -- almost 10 times as much product -- would receive a minimally greater base offense level of 8. FDA believes this result would not adequately deter mid-level and high-level hGH distributions.

FDA's recommended unit conversion would effectively deter illicit conduct by matching sentencing to the quantity of hGH being illicitly distributed by an individual defendant and would result in a meaningful distribution of offenders based on the quantity of hGH they distribute. Moreover, this result is consistent with Congress's intention that illegal hGH distribution be punished as a five year felony, similar to anabolic steroids and other Schedule III controlled substances. See 21 U.S.C. § 333(e).

3. Maximum Base Offense Level

Although FDA is concerned that a maximum base offense level could hinder the prosecutions and punishments of very large scale distributors, it does not oppose a maximum base offense level for hGH offenses equal to that for anabolic steroids. As discussed above, hGH

⁶ FDA has encountered a few illegal hGH distribution schemes that exceed the numbers in Figure 1. These illegal distributions involve large entities and multiple individuals, rather than the typical illegal distribution schemes described above. Such entities and individuals would likely reach a cap of 20 (see infra Section I.C.3.) regardless of the unit conversion.

⁷ See supra note 3.

trafficking is very similar to, and often occurs with, anabolic steroids trafficking, and the adverse effects of hGH pose a danger that is equal to danger posed by the adverse effects of anabolic steroids.

4. Enhancements And Modifications

FDA also urges the Commission to expand the scope of § 2D1.1(b)(7) to include a two-level enhancement if the distribution involved hGH and a masking agent, and to expand the scope of § 2D1.1(b)(8) to include a two-level enhancement if the defendant distributed hGH to an athlete. FDA also urges the Commission to modify Application Note 8 to instruct the court to apply the adjustment in § 3B1.3 for abuse of trust in cases where a coach uses his or her position to influence an athlete to use hGH.

Until recently, FDA had no opinion as to whether an enhancement should be added for the distribution of a masking agent because it was not aware of any testing for hGH, and thus, it was not aware of a need for a masking agent for hGH testing. However, Dr. Gary I. Wadler, a member of the World Anti-Doping Agency and a spokesman for the American College of Sports Medicine, has recently indicated that a blood test for hGH will soon be ready. See Stephanie Nano, Growth Hormones Don't Boost Performance, ASSOCIATED PRESS, March 17, 2008. The development of such tests will no doubt promote the development of masking agents to circumvent those tests. Therefore, while FDA is not currently aware of a masking agent for hGH, it anticipates that a masking agent will be developed not long after testing for hGH usage begins.

FDA also urges the Commission to add an enhancement if the defendant distributed hGH to an athlete. Because hGH is perceived as an easy way to increase athletic performance, it is particularly subject to abuse by both amateur and professional athletes. An April 1997 Sports Illustrated article called the use of performance enhancing substances, including hGH, the "dirty and universal secret of sports, amateur and pro, as the millennium draws near." Michael Bamberger and Don Yeager, Over the Edge: Aware that Drug Testing Is a Sham, Athletes Rely More than Ever on Banned Performance Enhancers, SPORTS ILLUSTRATED, Apr. 14, 1997, at 60. Also, former Senator George Mitchell, in his recent report to the Commissioner of Major League Baseball, discusses accusations made against numerous professional baseball players for purchasing and/or using hGH. See George J. Mitchell, Report to the Commissioner of Baseball of an Independent Investigation Into the Illegal Use Of Steroids And Other Performance Enhancing Substances By Players In Major League Baseball, December 13, 2007 at 145-230. Many of the professional baseball players who allegedly purchased and/or used hGH also allegedly purchased and/or used anabolic steroids. See *id.* Therefore, it appears that hGH is being abused by both amateur and professional athletes and should be addressed by an appropriate enhancement under the guidelines.

The allure of the perceived benefits of hGH on athletic performance cannot be limited to athletes. Indeed, it is safe to assume that coaches may also be seduced by hGH's perceived benefits on an athlete's performance. Coaches are driven to produce favorable results, and the pressures to achieve those results may lead them to facilitate the distribution of hGH to one or more of their athletes. Such behavior is especially heinous because coaches have great access to

their athletes and are in a unique position of authority and trust over them. The abuse of that position should be deterred and appropriately punished. Accordingly, FDA recommends that the Commission modify Application Note 8 for §2D1.1 to expressly instruct the court on how to apply § 3B1.3 (Abuse of Position of Trust or Use of Special Skill) in a situation in which a coach used his or her position to influence an athlete to use hGH.

D. Conclusion

FDA fully supports the Commission's proposal and believes that it will significantly improve the government's ability to combat and prosecute illegal distributions of hGH. FDA also believes that its recommendations in response to the Commission's specific requests for comment are consistent with Congressional intent for sentencing hGH offenses, will result in fair and appropriate sentences, and would further FDA's public health mission by deterring the illegal distribution of hGH.

II. PRESCRIPTION DRUG MARKETING ACT VIOLATIONS

The Prescription Drug Marketing Act (PDMA) prohibits, among other things, the unlicensed wholesale distribution of prescription drugs; the sale, purchase, or trading of prescription drug samples and coupons; and the reimportation by anyone other than the manufacturer of prescription drugs manufactured in the United States. Congress enacted the PDMA to prevent the distribution of counterfeit, misbranded, adulterated, or expired prescription drugs to American consumers. See H.R. Rep. No. 100-76 at 2 (1987). The PDMA is primarily aimed at preventing prescription drug diversion, which threatens the integrity of the nation's drug supply. Congress concluded that the various forms of prescription drug diversion created an "unacceptable risk" that counterfeit or substandard drugs would be sold to American consumers. Id. The recent passage of the FDA Amendments Act of 2007 (FDAAA) demonstrates that Congress remains concerned about the serious risk that drug diversion poses to the health of the American consumer; FDAAA directs the FDA to devote additional resources and to undertake enhanced enforcement efforts to combat drug diversion and counterfeiting and to protect the prescription drug supply chain. See 21 U.S.C. § 355D.

A. Existing Guidelines for PDMA Offenses

As stated in the written testimony previously submitted to the Commission, the conduct that is typically subject to criminal prosecution under the PDMA presents a significant public health risk. Illicit prescription drug diverters are driven by greed and create a risk to the public health by distributing drugs, often obtained from questionable sources, that may be stolen, unapproved, expired, counterfeit, or otherwise substandard. This public health risk is compounded by the fact that illicit diverters generally lack the motivation to store and handle prescription drugs properly; improper storage and handling can adversely affect the drugs' potency, stability, and effectiveness. Ultimately, these diverted drugs end up on the shelves of pharmacies for dispensing to consumers who remain unaware that the drugs came from an illicit and potentially dangerous source. Offenders who violate the PDMA undermine the integrity of the prescription drug supply and place the health and safety of American consumers at risk.

Congress believed that certain knowing violations of the PDMA presented a sufficient public health risk to warrant a statutory maximum sentence of ten years in prison. 21 U.S.C. § 333(b)(1). In contrast, most other felony violations of the Federal Food, Drug, and Cosmetic Act are subject to a maximum sentence of three years in prison and require proof that the offender acted with intent to defraud or mislead. 21 U.S.C. § 333(a)(2). Despite these differences, the existing sentencing guidelines do not distinguish between these PDMA offenses and other FDCA violations.

FDA believes that the existing guidelines do not provide for adequate sentences for most PDMA violations. In fact, in FDA's experience, prosecutors often are reluctant to charge PDMA violations due to inadequacies and uncertainties in the existing guidelines. As a result, many PDMA violations investigated by FDA's Office of Criminal Investigations are not prosecuted; criminal charges are sometimes pursued only if FDA is able to demonstrate a violation of other criminal statutes.

One problem with the existing guidelines is the requirement that the government prove that the offense involved fraud in order to obtain an enhancement above the base offense level of 6 provided for in § 2N2.1. In many cases, offenders knowingly violate the PDMA without committing clearly demonstrable fraud and courts, therefore, may not apply the cross-reference to § 2B1.1. For example, when an unlicensed wholesale distributor sells diverted prescription drugs to another wholesale distributor, the recipient wholesaler often is aware that the wholesaler from whom he purchased the drugs is not licensed and that the drugs may have come from an illicit source. The unlicensed wholesale distributor has committed a knowing violation of the PDMA, but the court may not find that the offense involved fraud if the defendant has not misrepresented his licensing status or the source of the drugs to the purchaser and has not taken affirmative steps to conceal his conduct from FDA, state licensing authorities, or consumers. Thus, courts may not apply the cross-reference to § 2B1.1, even though the offense presents a potentially serious public health risk.

Even if a particular PDMA offense involves clearly provable fraud and the cross-reference to § 2B1.1 applies, the calculation of "loss" under 2B1.1 is problematic in most PDMA cases. Under § 2B1.1, "loss" means "pecuniary harm that resulted from the offense." USSG § 2B1.1 cmt. (3)(A). This definition ignores the non-economic public-health harm that is the primary focus of PDMA violations: the high risk that subpotent, adulterated, or counterfeit prescription drugs will enter the supply chain. For example, a defendant who violates the PDMA by engaging in unlicensed wholesale distribution of prescription drugs may sell genuine product or product from an unknown source that has been stored in the trunk of a car or repackaged under filthy conditions. Assuming that the offense involves fraud, the current guidelines do not provide clear guidance on whether the risk that the distributed drugs are substandard results in a loss under 2B1.1 and, if so, how that loss should be calculated.⁸

⁸ While many diverted drugs may be subpotent or otherwise contaminated as a result of the conditions in which they are manufactured, stored, or repackaged, it is often difficult for the government to prove that a particular drug is substandard. In many cases, either there is no reliable testing method to determine whether a particular drug has been compromised, or the drugs have already been distributed and are not available for testing.

B. Recommendations

This lack of clarity in the existing guidelines undermines FDA's ability to protect the nation's prescription drug supply by creating uncertainty for prosecutors who are considering whether to pursue PDMA violations. FDA supports any amendment scheme that would address these uncertainties and improve FDA's ability to use the criminal provisions of the PDMA to ensure the safety of the prescriptions drugs distributed to American consumers. Two possible solutions are discussed below.

One possible solution would be to amend § 2N2.1 to increase the base offense level for PDMA violations and include enhancements for specific conduct that increases culpability. If the Commission decides to amend § 2N2.1 to address PDMA offenses, FDA believes that a higher base offense level and certain specific offense characteristics would be necessary to ensure adequate offense levels for PDMA offenders. FDA suggests that § 2N2.1 be amended to provide a base offense level of 12 for PDMA violations subject to enhanced penalties under 21 U.S.C. § 333(b)(1). Proposed amendment language along these lines was included as an attachment to FDA's earlier written testimony. A base offense level of 12 would be appropriate because Congress has assigned a ten year statutory maximum to these offenses and because the only PDMA offenses addressed by this proposed amendment require knowing conduct that undermines the closed prescription drug distribution system and the safety and effectiveness of prescription drugs. We also note that a base offense level of 12 for these knowing PDMA violations would still permit defendants who accept responsibility, and who are not subject to the enhancements suggested below, to reduce their offense level pursuant to § 3E1.1 in order to be sentenced under Zone B and possibly avoid imprisonment.

The recommended specific offense characteristics mentioned above would be enhancements based on inadequate storage or handling of prescription drugs; the distribution of unapproved, previously dispensed, expired, or counterfeit drugs; the failure to maintain records; and the distribution of significant quantities of drugs. The enhancements correspond with motivating concerns that Congress addressed when it enacted the PDMA.

For example, Congress expressed concerns about the dangers associated with inadequate storage of prescription drugs. Furthermore, a great deal of the potential public health harm resulting from PDMA offenses derives from improperly stored drugs. Such diverted drugs risk contamination, becoming subpotent due to exposure to improper temperatures and/or light conditions, and failing to function effectively when purchased and used by unsuspecting consumers. The PDMA is aimed at preventing drug diversion precisely because of the risk that diversion will introduce subpotent or adulterated drugs into the distribution system. A significant enhancement is warranted when that risk is heightened by individuals holding prescription drugs under improper storage conditions.

Congress was also concerned with the distribution of substandard, expired, or counterfeit drugs to American consumers. Defendants who introduce such drugs into the prescription drug distribution system create a heightened health risk above and beyond defendants who distribute otherwise legitimate, FDA-approved, drug products in violation of the PDMA. Therefore, FDA

believes that an enhancement for the distribution of unapproved, expired, previously dispensed, or counterfeit drugs is appropriate.

In FDA's experience, the failure by a distributor to maintain distribution records is a strong indicator of an illicit source, prevents FDA from disrupting illicit channels of distribution, and inhibits FDA's ability to adequately investigate these offenses. Under the minimum guidelines for state licensing of wholesale prescription drug distribution, enacted by FDA pursuant to the PDMA, wholesale drug distributors must, under state licensing schemes, maintain records of all transactions regarding the receipt and distribution of prescription drugs. 21 C.F.R. 205.50(f). Thus, this proposed enhancement would be applicable only when a distributor violates both these minimum guidelines and knowingly violates the PDMA statutory provisions.

The actual or intended quantity of drugs distributed is another valuable index of the seriousness of the violation of the PDMA. Logically, the greater the quantity of drugs being knowingly distributed by an illicit source in violation of the PDMA, the greater the public health risk posed by that particular individual's illegal distribution. We suggest that the average retail value of the drugs be used in this enhancement calculation because it relates directly to the amount of drugs involved and the degree of public exposure to the harm posed by such drugs.

Under this proposal, a defendant in Criminal History Category I who knowingly committed a PDMA offense subject to enhanced penalties under 21 U.S.C. § 333(b)(1) and who received all of these proposed enhancements mentioned here would still only receive a resulting offense level of 30 (e.g., base offense level 12 for knowingly distributing + 4 for inadequately storing prescription drugs + 4 for distributing an illicit type of drugs + 2 for failure to maintain records of distribution + 8 for distributing over \$1,000,000 of prescription drugs), reducible to 27 following substantial assistance. This offense level, resulting in a 70-87 month range in the most extreme case, is clearly appropriate for the ten year statutory maximum (120 months), allowing more than adequate "head room" for upward movement as a result of criminal history or for upward departures based on individual case factors not captured by these proposed guidelines.

Another possible solution would be to amend § 2N2.1 to provide a cross-reference to § 2B1.1 for knowing PDMA offenses subject to ten year maximum sentences under 21 U.S.C. § 333(b)(1) (without necessitating a showing of fraud) and to amend § 2B1.1 to clarify the appropriate calculation of loss. Specifically, the Commission could amend § 2N2.1(b)(1) to read: *If the offense involved fraud or involved a violation subject to 21 U.S.C. § 333(b)(1), apply § 2B1.1 (Theft, Property Destruction, and Fraud)*. This would ensure that § 2B1.1 would govern the PDMA offenses subject to the higher statutory penalties.

To clarify the calculation of loss under § 2B1.1, Application Note 3(F)(v) to § 2B1.1 could be amended to add subsection (IV): *goods sold in violation of a statutory or regulatory requirement, . . .* to ensure that no credit is given to the offenders for drugs sold in violation of the PDMA. To clarify what value should be used to determine loss, the following concluding sentence could be added to the application note: *For offenses involving violations of 21 U.S.C. § 331(t), loss shall include the average retail price of the drugs involved in the offense.* In the context of "loss," FDA feels the best representation is the retail price that would have been paid

for diverted drugs by the unknowing consumer whose health is placed at risk by the receipt of contaminated or subpotent drugs.

These suggested solutions are by no means exclusive, and FDA is amenable to other approaches that would address the concerns raised herein and more accurately reflect Congressional intent. We believe that these or similar amendments would significantly increase the effectiveness of the PDMA as a means to protect the public health, and would promote fairness by providing for consistent sentences for like offenders.

III. THE INADEQUACY OF EXISTING GUIDELINES FOR FDCA OFFENSES

The Commission has also proposed two specific amendments to the existing guidelines that relate to FDCA offenses and called for comment related to whether § 2N2.1 adequately addresses the numerous statutes currently referenced to that guideline. FDA supports both proposed amendments and welcomes the opportunity to address what we believe are some of the particular inadequacies of § 2N2.1.

A. Proposed Upward Departure Provision For Substantial Risk Of Injury Or Death

FDA supports the Commission's proposal to add a comment to § 2N2.1 recommending an upward departure if an offense "created a substantial risk of bodily injury or death." For FDA, "the public health" is not an abstract concept but translates all too readily into precisely the risks of bodily injury and death identified here. FDA's Office of Criminal Investigations typically focuses on defendants whose conduct poses a demonstrable risk to the public health and hence creates a substantial risk of injury or death to individual members of the public. As a result, many cases presented for criminal prosecution by FDA involve a substantial risk of bodily injury or death.

By way of example, in 2006 a federal district court sentenced two defendants for the illicit manufacture and distribution of dextromethorphan (DXM) that had resulted in the deaths of at least five individuals known to have bought these drugs from defendants. Although the top of the guidelines range was 61 months, United States District Judge John Tinder sentenced the defendants to 77 consecutive months based largely on the public health harm that occurred. See United States v. Johnson, 471 F.3d 764, 765 (7th Cir. 2006). One defendant appealed the sentence, but Judge Posner, writing for the Seventh Circuit, agreed that the trial court's upward departure from the Guidelines range was appropriate given the defendant's disregard for the risk of harm his actions created for members of the public. Id.

After United States v. Booker, 543 U.S. 220 (2005), such an upward departure is not likely to be overruled by an appellate court on legal grounds. However, as Suzanne Ferreira confirmed in her recent testimony before the Commission on behalf of the Probation Office, it is also true that such upward departures are more likely to occur in the presence of a comment from the Commission recommending them under specific circumstances. In short, even though upward departures are always possible under the current guidelines where a significant risk of injury or death is present, FDA feels that the Commission's proposed comment explicitly recommending such a departure will encourage judges to depart upward in appropriate

circumstances, as Judge Tinder did in Johnson, where a significant risk to the public health is present.

While an upward departure is preferable to the current guidelines structure, it is also important to recall that violations involving the risk of harm to the public represent the cornerstone of FDA's criminal enforcement actions under the FDCA. As such, we believe that a specific offense characteristic may be a more appropriate way to address the need to sentence defendants who inflict such a risk on the public because, unfortunately, this risk is present in a significant number of FDCA criminal cases. Because a risk of harm is present and demonstrable in many FDCA violations, particularly those for which FDA seeks criminal prosecution, we believe that a specific offense characteristic would be a more appropriate and consistent vehicle to guide sentencing in this class of cases on an ongoing basis. Despite our belief that a specific offense characteristic would be useful in this area, the recognition through the proposed comment that the risk of harm warrants an upward departure would be a very positive step toward more appropriate sentencing.

B. Proposed Specific Offense Characteristic For Second-Offense Violations

The Commission has also proposed adding a specific offense characteristic that would enhance the offense level of defendants with previous convictions under the FDCA. The Commission requests comments on the amount of the enhancement, providing a range of between two and seven levels. FDA supports the addition of this specific offense characteristic and believes that a seven (7) level enhancement for offenders with a prior FDCA convictions is appropriate.

FDA agrees with the Commission's suggestion that second time violators of the FDCA warrant a specific enhancement. Not only do these violators have a heightened level of knowledge with respect to the FDCA that should allow them to avoid reoffending should they choose to do so, but Congress expressly authorized a more severe punishment for violators of the FDCA who had already sustained a previous conviction. Compare 21 U.S.C. 333(a)(1) to 333(a)(2) (authorizing a three year statutory maximum rather than a one year maximum for the offense if the defendant has been previously convicted for an FDCA violation). As a result, we believe that the Commission's proposed enhancement is consistent with Congress's explicit recognition of the need for higher sentences for this group of violators and with the heightened need to deter such repeat offenders.

Because the proposed enhancement would only apply to individuals who had already been convicted of an offense under the FDCA, FDA believes that a seven (7) level enhancement is appropriate. Repeat offenders cannot reasonably claim ignorance of the legal requirements of the FDCA and demonstrate, by their recidivism, a disregard of their responsibility to ensure that the products that they distribute to American consumers are safe, uncontaminated, and otherwise compliant with the FDCA. Where a first time FDCA offender may claim a lack of awareness and violate without full knowledge of the illegality of his conduct, second offenders have received a significant warning by way of their prior criminal conviction and demonstrate that the prior punishment was not an adequate deterrent. Repeat offenders not only place the public

health at risk by again violating the FDCA but also do so with a much greater understanding of what constitutes violative conduct and its potential public health consequences.

As a result, this class of violators may be among the most culpable of FDCA offenders -- placing the public health at risk for a second time despite having already been warned by way of a criminal conviction of an FDCA offense. As discussed above, Congress has recognized the need to punish repeat offenders significantly more severely by providing harsher statutory penalties for repeat violators. In addition, the United States Supreme Court has recognized the appropriateness of punishment for individuals "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" because the consuming public is "wholly helpless" to ensure the safety of these products themselves. United States v. Park, 421 U.S. 658, 672 (1975) and United States v. Dotterweich, 320 U.S. 277, 285 (1943). Therefore, FDA believes it is appropriate for the Commission to apply a seven (7) level enhancement to this end to ensure that offenders who twice show disregard for the public health by violating the FDCA face prison time.

C. Inadequacy of Section 2N2.1 For FDCA Violations

As mentioned earlier in this section, the Commission has requested comment regarding whether the existing guideline at § 2N2.1 (with its cross-reference to § 2B1.1) is adequate to address the numerous statutes currently referenced to that guideline.⁹ As the Commission is aware, seventy two (72) separate statutory provisions are currently sentenced under § 2N2.1, and the breadth of substantive violations that § 2N2.1 currently addresses is extremely varied. There are more than 30 separate prohibited acts under the FDCA, each of which individually encompasses a large range of conduct. For example, one provision of 21 U.S.C. § 331 prohibits the introduction of a misbranded or adulterated food, drug, device, or cosmetic into interstate commerce. Because "misbranded" and "adulterated" are statutorily defined terms as well, this single prohibited act covers conduct that ranges from failure to include a drug's expiration date on the labeling of a product shipped interstate to the interstate shipment of a food containing a lethal chemical left in the product following improper manufacturing.

Violations of the FDCA range widely, from instances of application fraud directed at FDA's regulatory process of drug and device approval to the dispensing of a prescription drug without a valid prescription, from counterfeiting of drugs to the failure of clinical investigators to maintain accurate case records. Each of these divergent violations of the law, despite their varying degrees of implications for the public health, is currently sentenced under § 2N2.1. While we recognize the magnitude and complexity of reforming § 2N2.1 in order to sentence such a broad range of conduct more appropriately, FDA believes that the current guidelines are inadequate to address the wide variety of FDCA offenses and their significantly varying implications for the public health.

⁹ In general, any violation of the FDCA is a misdemeanor punishable without any showing of criminal intent by a maximum prison term of one year. 21 U.S.C. § 333(a)(1). A violation of the FDCA that is committed with the intent to defraud or mislead either consumers or a government agency, or that is a second conviction under the FDCA, is a felony with a maximum prison term of three years. 21 U.S.C. § 333(a)(2). Both of these violations are sentenced under § 2N2.1.

The current guidelines treat FDCA misdemeanor violations as relatively minor regulatory offenses with a base offense level of 6, with no enhancements for specific offense characteristics. The problem with the low base offense level is compounded by the lack of enhancements for specific offense characteristics under § 2N2.1. Misdemeanor violations of the FDCA encompass a wide range of conduct, from strict liability record-keeping offenses to the willful distribution of dangerous products that could seriously injure or kill consumers. For example, FDA investigates the distribution of drugs, biologics, and medical devices that have not been approved by FDA. In the most egregious cases, these offenses involve the sale of unproven, potentially dangerous drugs to seriously ill patients who may forego FDA-approved treatments. Other cases involve the dispensing of prescription drugs without a valid prescription, which presents a health risk to consumers who may not be aware of potentially dangerous drug effects and interactions and may forego diagnosis by a licensed physician. Although these offenses may lack fraudulent conduct, they can inflict serious harm on large numbers of people.

FDA believes that Section 2N2.1 is inadequate to address the wide ranging degrees of culpability that may occur in FDCA misdemeanors. Despite the lack of fraud, the conduct addressed in these situations fully warrants prosecutorial attention and meaningful redress by the courts. FDA-regulated products are vital to society, and consumers expect and assume that the products will be safe, pure, and effective. The current guidelines should be amended to provide for stiffer sentences for misdemeanor offenses that, while not involving fraud, involve a cognizable risk to the public health or knowing, intentional, or willful conduct.

While felony violations of the FDCA are cross-referenced to § 2B1.1, this cross reference does little to address the seriousness of felony conduct in several categories of cases where the focus of the fraudulent activity does not generate significant or demonstrable monetary loss to identifiable victims. Although the application of the fraud guideline to felonies under § 2B1.1 may provide appropriate punishment when the offense involves significant pecuniary loss, this cross reference to § 2N2.1 does not address the underlying public health purposes of the FDCA and does not provide for an appropriate range of sentences for those offenses that do not involve pecuniary loss commensurate with their public health harm.

Therefore, beyond the proposed additions to § 2N2.1 provided in the Commission's call for comment, we also recommend that the Commission consider addressing two other areas where the existing guidelines are inadequate. Amendments to address the two issues described below would go a long way toward alleviating significant inadequacies in the current guidelines, although we recognize that the complexity of sentencing the breadth of FDA and other offenses under §2N2.1 will remain an issue. Nonetheless, we feel that the areas identified below warrant particular and prompt attention.

1. Calculations of "Loss" for Adulterated or Misbranded products

Most FDCA offenses involve FDA-regulated products that are adulterated or misbranded. A product may be adulterated or misbranded for numerous reasons set forth in the FDCA. For example, a drug or medical device is adulterated if, inter alia, it is not manufactured in conformance with good manufacturing practice or if it is prepared or held under insanitary conditions whereby it may have been contaminated with filth or rendered injurious to health.

See 21 U.S.C. § 351. A drug or medical device is misbranded if, inter alia, its labeling is false or misleading in any particular or if its labeling fails to bear adequate directions for use. See 21 U.S.C. § 352. Misbranded or adulterated products may not lawfully be introduced into or received in interstate commerce and are subject to seizure and destruction under 21 U.S.C. § 334. The existing guidelines, however, do not directly address whether misbranded or adulterated FDA-regulated products can nevertheless be viewed as having value when loss is calculated under § 2B1.1.

We suggest revising the Application Notes to § 2B1.1 to provide that, for the purposes of calculating loss for offenses involving FDA-regulated products that are adulterated or misbranded within the meaning of the FDCA, loss includes the amount paid for the product, with no credit provided for the claimed value of the product. This would be consistent with current Application Note 3(F)(v), which provides that, in cases involving products that require but lack regulatory approval by a government agency, the loss includes the full amount paid for the product with no credit for the value of the product.¹⁰ This amendment would also be consistent with the approach taken by the court in United States v. Gonzalez-Alvarez, 277 F.3d 73, 77-80 (1st Cir. 2002), which held that adulterated milk that cannot lawfully be sold has a value of zero for the purposes of calculating loss under the guidelines. Moreover, because there may remain some uncertainty between federal courts as to how to calculate loss for adulterated or misbranded products,¹¹ a comment from the Sentencing Commission would help to alleviate any existing confusion. We believe that including an application note that clarifies that, for sentencing purposes, misbranded or adulterated FDA-regulated products have no value would promote consistent application of the guidelines and would help ensure that the sellers of these illegal and often dangerous products receive adequate punishment.

2. Non-Monetary Fraud On The Public Health

Certain FDCA offenses do not necessarily involve any pecuniary loss but significantly undermine FDA's mission and thereby jeopardize the health and safety of the American public. The existing guidelines do not, in FDA's view, adequately address these offenses. For example, fraud related to a clinical trial, such as incomplete and false recordkeeping or using inappropriate patient populations to study a drug, does not necessarily involve any significant pecuniary loss but severely undermines the reliability of FDA's drug and device approval process and thereby jeopardizes the health and safety of the American public. Several other felony offenses involve a similar fraud on FDA's regulatory process, such as the failure to report adverse drug events and

¹⁰ While the current Application Note addresses unapproved drugs, it does not address drugs that are adulterated or misbranded.

¹¹ The question of how to measure "loss" under § 2B1.1 for a misbranded or adulterated product remains an unsettled issue. Although the recently added Application Note to 2B1.1 at 3(F)(v) settles the issue for unapproved products, the question of appropriate loss evaluation remains an unnecessary source of contention for misbranded and adulterated products. Compare, e.g., United States v. Marcus, 82 F.3d 606, 610 (4th Cir. 1996) (finding that whether a loss exists for sentencing purposes hinges on whether a modification to a drug's formula was significant) with United States v. Gonzalez-Alvarez, 277 F.3d 73, 77-80 (1st Cir. 2002) (holding adulterated milk without value for the purposes of the loss calculation).

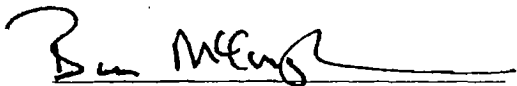
the failure to comply with medical device reporting requirements. This category of offenses poses a significant risk to the public health by undermining the basis for FDA's approval and regulatory decisions, but the harm they inflict is not readily monetized or understood as pecuniary loss. As a result, the harm resulting from this category of cases is not effectively captured by existing guidelines. Although fraudulent conduct is involved and § 2B1.1 is applicable (through the § 2N2.1 cross-reference), no significant enhancement occurs because the fraud does not result in a demonstrable pecuniary loss.

Because the currently available enhancements do not track the seriousness of this category of conduct and its implication for the public health, amendments to capture that harm are necessary in FDA's view. We are aware that other commentators have suggested establishing a Working Group to discuss the specific means of implementing guidelines amendments to address these inadequacies, and FDA welcomes the opportunity to participate in that process, should the Commission believe it to be appropriate here.

IV. CONCLUSION

We greatly appreciate this opportunity to provide our comments regarding the Commission's current proposals and commend the Commission members for their time and attention to the guidelines governing criminal offenses enforced by FDA. As the Commission has recognized by its inclusion of these issues in this year's amendment cycle, the effective sentencing of food and drug offenses affects all of us in numerous and important ways. FDA looks forward to continuing to work with the Commission to provide any additional assistance that would be useful.

Sincerely,

A handwritten signature in dark ink, appearing to read "Wm McConagha", followed by a horizontal line.

William A. McConagha
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March 6, 2008

Honorable Ricardo H. Hinojosa
Chair
United States Sentencing Commission
One Columbus Circle, N.E.
Suite 2-500, South Lobby
Washington, D.C. 20002-8002

Re: Comments on Proposed Amendments

Dear Judge Hinojosa:

With this letter, we provide comments on behalf of the Federal Public and Community Defenders regarding the proposed amendments to the United States Sentencing Guidelines, published on January 28, 2008.¹ We also provide our comments on the proposed amendments to the Commission's Rules of Practice and Procedure as they pertain to the Commission's consideration of retroactivity.²

I. IMMIGRATION

A. In general

At the outset, we commend the Commission for its commitment to addressing the complex application problems that plague the current § 2L1.2. We appreciate the ongoing efforts in this area and are hopeful that the ultimate result will be a guideline that is both simpler to apply and a fairer reflection of the purposes of sentencing under 18 U.S.C. § 3553(a). However, given the ongoing national debate about federal immigration law and the inevitable changes to come with a new Administration, we believe that the Commission should not amend § 2L1.2 during this cycle. Instead, we urge the Commission to wait until stability has been established, after which we can begin work on a long term and comprehensive solution that is consistent with national policy.

Whether the Commission addresses § 2L1.2 this year or next, however, we wish to reiterate the Federal Defender community's longstanding view that the guideline, by including a broad 16-level enhancement for prior convictions, produces sentences that are

¹ 73 Fed. Reg. 4,931 (2008).

² 73 Fed. Reg. 4,939 (2008).

simply too high.³ In our view, the guideline, if followed, contravenes the “overarching provision instructing district courts to ‘impose a sentence sufficient, but not greater than necessary,’ to achieve the goals of sentencing.” See *Kimbrough v. United States*, 128 S. Ct. 558, 570 (2007). While data provided by the Commission indicates that Options 2 and 3 would reduce some of the more severe sentences,⁴ we are concerned that for every variation of every option, sentences would significantly increase for many defendants at the lowest offense levels. There is no policy reason why sentences should be increased for those who are the least culpable.

As the Commission has recognized, the original guideline for illegal reentry was largely based on past practice, but subsequent revisions to the guideline, beginning in 1988 and including the 16-level enhancement in 1991, caused penalties to soar, with the average length of sentences nearly tripling between 1990 and 2001.⁵ The Commission has never justified, either with empirical data or any policy analysis based on national experience, the 16-level enhancement in § 2L1.2, even though this enhancement is far more severe than other increases that depend on prior convictions. In the absence of empirical data or experience, § 2L1.2 does not “exemplify the Commission’s exercise of its characteristic institutional role.” *Kimbrough*, 128 S. Ct. at 567, 574-75 (discussing crack cocaine guideline). Accordingly, while we recognize that the driving force behind the current proposals is the Commission’s immediate interest in a certain degree of simplification, we believe that the Commission should not amend § 2L1.2 without also reviewing its fundamental premises and reducing the penalties themselves.

The actual sentences imposed, including the widespread use of government-sponsored downward departures, demonstrate that the current guideline is greater than necessary to achieve the goals of sentencing under § 3553(a)(2). For example, in 2006, based on motions by the government and determinations by the courts, 36.5% of sentences imposed for illegal reentry were lower than the advisory guideline range, not including sentences reduced for substantial assistance under § 5K1.1.⁶ In contrast, only 15.6% of offenders sentenced for crack cocaine received sentences lower than the advisory guideline range (excluding reductions for substantial assistance),⁷ despite the

³ See, e.g., Letter from Jon Sands to Hon. Ricardo Hinojosa, Re: Proposed Priorities for 2007-2008, at 19 (July 9, 2007); Letter from Jon Sands to Hon. Ricardo Hinojosa, Re: Proposed Amendments Relating to Immigration at 3-4 (Mar. 2, 2007); Testimony of Jon Sands and Reuben Cahn before the U.S. Sentencing Commission Re: Proposed Immigration Amendments, San Diego, California (Mar. 6, 2006).

⁴ See Memorandum from Kevin Blackwell to USSC Immigration Team, *Impact of Proposed Amendments to §2L1.2(Unlawfully Entering or Remaining in the United States)* (Feb. 29, 2008). The Commission was not able to perform an analysis of the impact of Option 1. *Id.* at 1.

⁵ See United States Sentencing Comm’n, *Fifteen Years of Guidelines Sentencing: An Assessment of How Well the Federal Criminal Justice System is Achieving the Goals of Sentencing Reform*, at 61-65 (Nov. 2004) [“Fifteen Year Report”].

⁶ United States Sentencing Comm’n, *2006 Sourcebook of Federal Sentencing Statistics*, tbl. 28 (2006).

⁷ *Id.* tbl. 45; see also United States Sentencing Comm’n, *2007 Sourcebook of Federal Sentencing Statistics*, tbl. 28 (2007) (showing similarly divergent rates of below-guidelines sentences for illegal reentry (31%) and offenses involving crack cocaine (15%) for fiscal year 2007). Preliminary statistics indicate that the rate of below-guideline sentences has increased to 38% since *Gall* and *Kimbrough* were decided. See United States Sentencing Comm’n, *Preliminary Post-Kimbrough/Gall Data Report*, tbl 4 (Feb. 2008).

Commission's own view that guideline sentences for crack cocaine are too harsh and result in unwarranted disparities.

In short, reducing the more severe sentences without raising the sentences for the least culpable should be a primary objective underlying any amendment to § 2L1.2. In aid of that goal – and the overarching goal of achieving the purposes of sentencing – we summarize what we believe should also be included as the Commission's primary objectives when it amends § 2L1.2:

- If kept, the 16-level enhancement should be reserved for only the *most serious* of the offenses that fall into the category of "aggravated felonies" under 8 U.S.C. § 1101(a)(43).
- Prior convictions used to increase a defendant's offense level should be subject to the same remoteness rules in Chapter 4 to reflect more accurately Congress's intent to deter and increase punishment for those individuals who present the most serious risk of recidivism.
- The Commission should take into consideration, as a factor, the existence of "fast-track" dispositions in any amendment to the immigration guidelines. The "fast-track" dispositions clearly indicate the true seriousness of many offenses, which is markedly lower than current guidelines. Considering "fast-track" sentences also would address the problem of unwarranted disparity for those similarly situated defendants in nonfast-track districts.
- For every Chapter Two guideline that relies on prior convictions (and for calculation of criminal history), the Commission should use "sentence served" instead of "sentence imposed." "Sentence served" is a truer marker of culpability than "sentence imposed" because it reflects the real deprivation of liberty intended by the state sentencing authority. It would also lessen the effect of triple counting prior offenses in § 2L1.2 cases, first for increasing the statutory maximum for "aggravated felony," second for criminal history, and third for recency.
- The Commission should eliminate criminal history points for status and recency for defendants arrested for illegal reentry while they are serving a prison sentence. *See* USSG § 4A1.1(d), § 4A1.1(e). This would help avoid unfair double- and triple-counting of the same conduct.
- The Commission should add an application note suggesting bases for downward departure, such as overrepresentation of criminal history and a defendant's benign motives for the reentry (e.g., defendants who return for medical or humanitarian reasons, due to dangerous conditions in the

defendant's country of origin, or because of cultural assimilation into the United States).

B. Our Proposal

We previously submitted a proposed guideline modeled on the guideline for prohibited persons in possession of firearms, USSG § 2K2.1.⁸ Our proposal is premised on the fact that both offenses, illegal possession of a firearm and illegal reentry, are enhanced based on the nature of the defendant's prior convictions, but that the potential harm to the community of a felon's possession of a firearm is far greater than the potential harm resulting from illegally re-entering the United States. Our proposal retains an enhancement for defendants who enter the United States in connection with the commission of a national security or terrorism offense, and notes that a downward departure may be warranted where the defendant has returned because of family medical needs or because the defendant was culturally assimilated into the United States.

Although our proposal was not included as one of the options published for comment for this amendment cycle, we believe that it deserves consideration. First, our proposal both addresses application problems presented by the current proposals and reflects the sound policy that Chapter Two guidelines that set offense levels based on prior convictions should have a similar structure while appropriately calibrating punishment to the relative harms involved. Second, the Commission has provided data on its potential impact on sentences, which indicates that our proposal would reduce sentences overall. Like Options 2 and 3, however, it would raise some sentences for the least culpable defendants, though to a significantly lesser degree than Options 2 and 3. Because there is no reason to raise any sentences for illegal reentry, we hope to work with the Commission to discover the reason that our proposal would raise some sentences and then amend it accordingly.

Finally, we remain open to modifications to our proposal that address the goal of simplification (for example, our proposal does not define "crime of violence" in accordance with 8 U.S.C. § 1101(a)(43), as Option 1B of the proposed amendments would do).

C. The Proposed Amendments

In light of our general position, we hesitate to comment at length on the Commission's proposals because they leave unaddressed many of the most fundamental problems presented by § 2L1.2. However, we would like to point out several ambiguities and problems presented by the proposed amendments – areas that invite more questions than are answered and are of particular concern to the Defender community.

⁸ See Letter from Jon Sands to Hon. Ricardo Hinojosa, Re: Proposed Priorities for 2007-2008, at 21-23 (July 9, 2007).

Option 1

The Commission was not able to conduct an impact analysis for Option 1 with the available data. Without knowing whether Option 1 would reduce the most severe sentences without raising the least, we nevertheless provide the following comments:

Option 1A

Option 1A not only fails to simplify, but increases complexity to § 2L1.2. By including new language and defining new terms, such as “forcible sex offenses,” Option 1A adds to the many statutory and guideline definitions that the court must consider in each case, exacerbating the confusion and creating yet more areas for litigation. *See, e.g., United States v. Gomez-Gomez*, 493 F.3d 562 (5th Cir. 2007), *reh’g en banc granted*, 2008 WL 373182 (5th Cir. Feb. 22, 2008) (considering the meaning of “forcible sex offense”). In addition, by retaining guideline-level enumerated categories of offenses that may constitute “crimes of violence,” Option 1A does little to address the application problems identified by many commentators, judges, and practitioners, ~~the participants of the Immigration Roundtable in Houston last September~~, who noted with frustration the complex litigation even in the mine run of cases.

Further, by amending the definition of “drug trafficking offense” to include transportation and offers to sell, Option 1A will increase sentences for a large number of defendants without any reasoned basis for doing so. There has been no empirical evidence, data, or policy reason offered to explain why sentences should now be increased across the board for every defendant convicted of these minor offenses. It is not enough to say that that on occasion, defendants sentenced under the current guideline do not receive a 16- or 12-level enhancement for a prior offense that might have been a drug trafficking offense.⁹ We cannot support an amendment that addresses unsupported speculation about “problems” created by the categorical approach in some cases by enhancing punishment for defendants not previously subject to an enhancement because the Commission did not view the prior conviction as a drug trafficking offense.

Option 1B

Option 1B appears to be a step in the right direction – at least as far as simplicity is concerned – in that it tends to eliminate some of the application problems identified at the Immigration Roundtable, streamlining the definition of “crime of violence” by referring to the controlling statute, 8 U.S.C. § 1101(a)(43), and defining “drug trafficking offense” as it is defined by 18 U.S.C. § 924(c)(2) and recently interpreted by the Supreme Court in *Lopez v. Gonzales*, 126 S. Ct. 625 (2006). These changes respond to comments

⁹ *See, e.g., United States v. Gonzales*, 484 F.3d at 412, 714-15 (5th Cir. 2007) (applying the categorical approach to Tex. Health & Safety Code § 481.112, the offense of “delivery of a controlled substance” includes the offense of “offering to sell a controlled substance,” and thus “lies outside section 2L1.2’s definition of ‘drug trafficking offense.’”); *United States v. Gutierrez-Ramirez*, 405 F.3d 352, 354 (5th Cir. 2005) (under the categorical approach, an unspecified conviction under Cal. Health & Safety Code § 11352(a), which includes transportation, does not constitute a “drug trafficking offense” under § 2L1.2).

from judges and practitioners alike who urged the Commission to eliminate the often incoherent results of the second-level guideline definitions for "crime of violence." In addition, the use of § 924(c) as the source of the definition of "drug trafficking offense" enjoys a level of certainty and some needed narrowing of covered offenses. However, we have several concerns.

Option 1B does not address the disproportionate severity of the guideline as a whole. Nor does it address stale convictions or the 16-level enhancement for alien smuggling, which many commentators view as particularly inappropriate in the mine run of cases. In those isolated cases in which aggravating circumstances occur, sufficient mechanisms for increased punishment are already in place. And we are wary of the wholesale incorporation of the definition of "drug trafficking offense" from § 924(c)(2) into the provision advising a 16-level enhancement, as that definition can reach simple possession of more than 5 grams of crack and cases with two prior convictions, including misdemeanors. *See* 21 U.S.C. § 844. Given the varying degrees of seriousness for these offenses, the Commission should exempt the least serious offenses covered by § 924(c)(2) from the 16-level enhancement.

Option 1 – Departure Considerations

Option 1 also proposes two departure considerations in Application Note 7. The first suggests an upward departure where a prior conviction for possession or transportation or offer to sell does not qualify for the 16-level enhancement because it is not a "drug trafficking offense" as defined by § 2L1.2, but the offense involved "a quantity of a controlled substance that exceeds a quantity consistent with personal use." In essence, this proposal invites judges to make factual determinations that second-guess the nature of a prior conviction as determined by the relevant jurisdiction, with the apparent purpose of "making up for" – through increased punishment for the illegal reentry – what a federal judge views as a "too-lenient" state sentence. Although we generally oppose incorporating these types of factual determinations into the advisory guidelines, we believe that should the Commission adopt such a departure provision in § 2L1.2, it must be mitigated by an Application Note that emphasizes the purpose of the system of graduated punishment for illegal reentry:

The purpose of the specific offense characteristics is to reflect the seriousness of the current offense. It is not to punish the defendant for a prior offense for which he or she has already been convicted and punished.

The second departure consideration in Option 1B suggests a downward departure where the prior conviction does not meet the definition of "aggravated felony" under § 1101(a)(43). We believe that any version of § 2L1.2, including the current guideline as written, should limit the 16-level enhancement under § 2L1.2(b)(1)(A) to convictions that meet the definition of "aggravated felony" under § 1101(a)(43). Otherwise, it should include a note such as the one in Option 1B suggesting a downward departure where the prior conviction does not meet the definition of "aggravated felony" under § 1101(a)(43).

Option 2

Option 2 avoids many of the application problems that currently complicate §2L1.2 by reducing the emphasis on the categorical approach and by linking the greatest single enhancement to national security or terrorism offenses or those "aggravated felonies" described in 8 U.S.C. § 1101(a)(43)(A). However, the data confirms that Option 2 would raise sentences for many of the least culpable defendants without any reason. Although we hesitate to comment at length given this fundamental problem, we point out several features that, in our view, raise serious concerns.

First, in subsection (b)(1), we believe it would be more appropriate to increase punishment if the defendant was convicted of a felony for which a sentence of *imprisonment* that exceeded 24 months was imposed. This is especially true if the ambiguous language of subsection (b)(3) means that other felony offenses could result in additional (and apparently limitless) increases, as appears to be the case under either option in proposed Application Note 3.

Second, subsection (b)(4) appears to shift the burden to the defendant to show that he or she has no prior felony convictions in order to receive a decrease in the offense level, a shift that violates principles of basic fairness and implicates constitutional questions of due process. Even worse, it places the burden on the party who is least able to obtain the information. Far from simplifying the process, subsection (b)(4) invites unnecessary litigation of constitutional proportion and should not be considered.

Third, we oppose the use of any conviction to enhance a sentence for illegal reentry that did not receive any criminal history points under the rules for computing criminal history points in Chapter Four, as directed by Application Note 2 of Option 2. The proposed structure of Option 2 is ambiguous as best, potentially allowing for stacked enhancements through the repeated application of subsection (b)(3) for old convictions or multiple convictions that were disposed of in single proceedings. Application Note 2 thus could operate to result in significantly higher sentences for illegal reentry based on a system that is not only out of sync with the Commission's view of the predictive value of criminal history under Chapter Four (or its relationship to culpability for the instant offense), but is not, as far as we know, based on any reasoned principles or empirical evidence related to the overarching purposes of sentencing for illegal reentry.

A similar criticism must be leveled against Application Note 3, Option B. That provision would greatly increase sentences that, in our view, are already too high. (It would, for example, set the offense level as high as 30 for a defendant convicted twice of minor drug offenses, even if one of them occurred decades earlier.)

Finally, we question the purpose of the upward departure consideration in Application Note 4. The note would invite an upward departure in cases in which the defendant has been removed multiple times before committing the offense of illegal reentry. In addition to raising serious due process concerns (along with the specter of

unwarranted disparity between defendants from contiguous and noncontiguous nations), such a departure provision is unnecessary. The Commission removed a similar provision from § 2L1.2 in 2001 when it restructured the guideline to provide for graduated punishment based on the seriousness of the prior offense.¹⁰ Although the Commission provided no specific reason for removing the provision, we note that in fiscal year 2001, it was applied in only two out of 6,121 cases (.03%) for which §2L1.2 was the primary guideline, an application rate that approached zero.¹¹ We presume that the Commission removed the provision after analyzing it in light of empirical data and the purposes of sentencing in 18 U.S.C. § 3553(a). That judges did not apply it further supports the conclusion that it was not necessary to achieve the purposes of sentencing. Reintroducing a similar provision at this time – in the absence of any new evidence or articulated policy reasons and when sentences are already too high – strikes us as particularly unsound.

Option 3

Option 3 is conceptually interesting, but should not be adopted at this time. It relies on a sentence-length approach, which is designed to eliminate many of application problems. However, like Option 2, Option 3 would raise sentences for the least culpable. Moreover, Option 3 retains several enumerated offenses that would require a guideline-level categorical approach, leading to complexity and litigation.

Although we have expressed interest in a sentence-length approach in the past, we recognize that it would represent a fundamental change in the structure of § 2L1.2, one that, if adopted here, might also reasonably be applied to firearms and other Chapter Two guidelines relying on prior convictions. In addition, we believe that before the Commission considers a sentence-length approach for § 2L1.2, it should both revisit criminal history in general, as we expect it will, and revisit the underlying premise of the 16-level enhancement. No matter what, we believe that Option 3B's requirement of a prior sentence of imprisonment exceeding 13 months in order to apply the enhancements under subsection (b)(1)(B)(iii) and (b)(1)(D) is the more appropriate approach, as it is consistent with Chapter 4.

We also note that Option 3 refers, in Application Note 3, to “related cases,” a concept that no longer exists in Chapter 4, having been replaced by the concept of “single sentences.” See USSG § 4A1.2(a)(2). The “single sentence” concept should be included in a new application note.

D. Issue for Comment

The Commission has asked for comment on whether any specific offense

¹⁰ See USSG App. C, Amend. 632 (Nov. 1, 2001) (deleting provision allowing for an upward departure in the case of “repeated prior instances of deportation”).

¹¹ See United States Sentencing Comm’n, 2001 *Sourcebook of Federal Sentencing Statistics*, tbls. 17 & 24 (2001).

characteristics and departure provisions in one option should be adopted by the Commission as part of another option. As we have indicated, we believe that any tinkering with § 2L1.2 should be delayed at least until the next amendment cycle, unless the Commission proposes revising the guideline to address all of its fundamental problems, not just a few application problems, while refraining from raising any sentences without sound policy reasons. For all of the reasons set forth above, we do not believe that any combination of the specific offense characteristics or departure considerations contained in the proposed amendments would achieve the needed reform of § 2L1.2.

Instead, we urge the Commission to take this time to consider our proposal, modeled on the guideline for § 2K2.1. Of course, we would be happy to discuss modifications to it that would advance the goal of simplicity and the overarching purposes of sentencing, but we believe it represents the best starting place.

II. CRIMINAL HISTORY

The Commission has proposed adding language to USSG § 4A1.2(a)(2) to modify the provision that exempts sentences that are separated by an intervening arrest from being counted as a single sentence. The proposed amendment states:

An "arrest" includes an attempted service of an arrest warrant where the defendant escapes the arrest or the service of the arrest warrant. The issuance of a summons or a complaint does not constitute an "arrest."

We see no need for this change. If any change is made, however, only the second sentence should be included.

The first sentence injects unnecessary complications into the guideline. We have been unable to find any reported case in which this issue has been presented. In the absence of any empirical evidence that this issue arises with any frequency, or that it presents an indication of an increased likelihood of recidivism, the Commission should omit this sentence.

Further, the language is so ambiguous that it is likely to lead to extensive litigation and evidentiary hearings. For example, could the government argue that a defendant "escapes" arrest or service of an arrest warrant if he is in fact not at home when the police arrive? If the police go to a home and are falsely told that the defendant is not there? What if police records reflect an inaccurate address, and the government argues that the defendant had previously given a false address? Would a defendant be subject to this provision if he or she moves without leaving a forwarding address? To what extent would the government have to prove that the defendant's actions were motivated by a desire to escape arrest, or that the defendant even knew that police were looking for him?

Although the second sentence does not create the same complications as the first, we likewise see no need for it. This point is clear in existing law. In *United States v.*

Joseph, 50 F.3d 401, 402 (1st Cir. 1995), the Seventh Circuit held that issuance of an arrest warrant could not be an “intervening arrest.” See also *United States v. Correa*, 114 F.3d 314, 316 n.3 (1st Cir. 1997) (not deciding whether the district court erred in treating issuance of a complaint as an intervening arrest, but describing that ruling as “problematic”).

The intervening arrest rule, which derives from the Parole Commission’s Salient Factor Score, presumably is “consistent with the Parole Commission’s recidivism research, as well as with the common sense notion that an offender who continues to commit offenses after criminal justice system intervention is more likely to recidivate.” Peter B. Hoffman & James L. Beck, *The Origin of the Federal Criminal History Score*, 9 Fed. Sent. R. 192 (1997). This rationale does not apply when a defendant escapes arrest, or when a complaint or summons is issued.

This minor issue aside, we remain hopeful that the Commission will soon turn its attention to the career offender guideline. In *Rita*, the Supreme Court emphasized that the guideline system is meant to be “evolutionary,” improved over time as a result of a reasoned dialogue among the district courts, the appellate courts, and the Commission. See *Rita v. United States*, 127 S. Ct. 2456, 2464-65, 2469 (2007) (“The reasoned responses of these latter institutions to the sentencing judge’s explanation should help the Guidelines constructively evolve over time, as both Congress and the Commission foresaw.”).¹² After *Booker*, the rate of below-guidelines sentences for those who otherwise qualified for career offender status markedly increased,¹³ and after *Gall* and *Kimbrough*, we can expect that courts will continue to exercise their wide discretion to sentence defendants below the advisory guideline range for career offenders until it more accurately advances the goals of sentencing under 18 U.S.C. § 3553(a).¹⁴ We urge the Commission to seize the opportunity to improve the career offender guideline – not only to reflect more precisely Congress’s directive to the Commission in 28 U.S.C. § 994(h), but also to reflect the empirical data it has collected demonstrating that the career offender guideline too often results in sentences that fail to advance the purposes of sentencing. See *Kimbrough*, 128 S. Ct. at 574-75.¹⁵

¹² See also Steven Breyer, *The Federal Sentencing Guidelines and the Key Compromises Upon Which They Rest*, 17 Hofstra L. Rev. 1, 18-20, 23 (1988).

¹³ United States Sentencing Comm’n, *Final Report on the Impact of United States v. Booker on Federal Sentencing*, at 137-140 (March 2006).

¹⁴ *United States v. Parker*, 512 F.3d 1037 (8th Cir. 2008) (recognizing that the district court has the discretion after *Gall* to sentence the defendant to 60 months, well below the advisory guideline range of 151-188 months under the career offender guideline under § 3553(a), and noting that the government withdrew its appeal in light of *Gall*); see *United States v. Marshall*, 2008 U.S. App. LEXIS 153, 22-23 (7th Cir. Jan. 4, 2008) (unpublished) (in a case involving a challenge to the career offender guideline, stating that it must “reexamine” its caselaw, in light of *Kimbrough*, in which it had previously held that courts are not authorized “to find that the guidelines themselves, or the statutes on which they are based, are unreasonable”).

¹⁵ Fifteen Year Report at 133-34 (career offender guideline “makes the criminal history category a less perfect measure of recidivism risk than it would be without the inclusion of offenders qualifying only because of prior drug offenses,” does not serve a deterrent purpose, and has a disproportionate impact on African-Americans); see *United States v. Pruitt*, 502 F.3d 1154, 1171 (10th Cir. 2007) (McConnell, J., concurring) (cited in *Kimbrough v. United States*, 128 S. Ct. 558, 575 (2007)) (“This might appear to be an

III. DISASTER FRAUD

The Commission seeks comment on whether it should permanently adopt the temporary amendments to § 2B1.1, which added a two-level enhancement if the offense involved fraud or theft in connection with a major disaster or emergency declaration benefit, and expanded the definition of “reasonably foreseeable pecuniary harm” to include the costs of recovering the benefit to any governmental, commercial, or non-profit entity. It also seeks comment on whether the amendment should be expanded to include contractor, sub-contractor or supplier fraud, and whether any aggravating or mitigating factors exist that would justify additional amendments.

We incorporate into this letter all of the comments we provided in our January 8, 2008 letter to the Commission’s legal staff, as well as the written and oral testimony of Marjorie Meyers, Federal Public Defender, Southern District of Texas, which was submitted to the Commission at the public briefing on February 13, 2008. We continue to believe that USSG § 2B1.1 already adequately accommodates the disaster related fraud offenses and thus oppose making the temporary amendment permanent. As with all other types of fraud, disaster related fraud offenses necessarily encompass a wide range of activity, from first-time offenses involving small amounts of funds to large-scale operations designed to defraud the government or others of millions of dollars. In the disaster-related context, offenders range from desperate victims of the disaster itself to con men ready to take advantage of the disaster and its victims.

A. Disaster Fraud Enhancements

As the experience of our clients demonstrates, many of the individuals prosecuted for disaster relief fraud after Hurricanes Katrina and Rita were themselves victims of the disaster. Many had little or no criminal record and are the sole support of their minor children. They stole to obtain the most basic necessities for survival or because they were manipulated by recruiters who took advantage of their desperate plight. They are not likely to offend again, and, for most, incarceration is a punishment greater than necessary to meet the purposes of 18 U.S.C. § 3553(a). In such cases, imposing a prison sentence could end up costing society more than the original crime, both because of the substantial costs of incarceration and because of the longer-term societal costs of failing to provide treatment for mental health issues or of removing the custodial parent from the care of her/his children.

A minimum base offense level above the already enhanced seven-level floor contained in § 2B1.1 (for offenses with a maximum statutory penalty of more than twenty years), will create “unwarranted *similarities*” among dissimilarly situated individuals. *See Gall v. United States*, 128 S. Ct. 586, 600 (2007) (emphasis in original). As related in detail in our testimony, individuals convicted of disaster-related fraud range from the

admission by the Commission that this guideline, at least as applied to low-level drug sellers like Ms. Pruitt, violates the overarching command of § 3553(a) that “[t]he court . . . impose a sentence sufficient but not greater than necessary, to comply with the purposes of sentencing set forth in’ § 3553(a)(2).”)

poverty-stricken, traumatized victims of the disaster to the fraudster who takes advantage of the desperation of both the victims and the service providers. Of note, the testimony of all parties presented to the Commission as well as our own experience reveals that the courts have rarely imposed sentences above the Guidelines in these cases, nor has the government sought any upward departure or variance. This is empirical evidence that the current Guidelines adequately take into account the § 3553(a) factors and there is no need to increase the base offense level in disaster related fraud cases.

Moreover, disaster relief is not limited to hurricanes. The President can declare an emergency for all manner of disasters ranging from hurricanes and earthquakes to drought or wild fires.¹⁶ A minimum offense level would all too easily condemn to prison the farmer who wrongfully obtains unemployment compensation while his crops wither on the vine, even though such a result would not serve the purposes of sentencing.

In addition, we urge the Commission to reconsider its decision to include as "reasonably foreseeable pecuniary harm" the administrative costs of recovering fraudulently obtained funds that are borne by any government or "or any commercial or not-for-profit entity." Congress did not direct the Commission to expand the concept of "pecuniary harm" in these cases or otherwise suggest that the existing standard was inadequate, and the Commission should hesitate before undertaking such an expansion on its own initiative. Calculating such costs will be difficult and costly with little likelihood of financial recovery given that many of these defendants are themselves indigent. It also seems entirely unnecessary. To our knowledge, full restitution has been ordered in all cases. Of course, should the aggrieved party remain unsatisfied by the restitution order in any particular case, it remains free to pursue civil remedies against the defendant.

B. Contractor, Sub-Contractor or Supplier Expansion

The Defenders do not typically represent people or entities accused of committing disaster benefit fraud offenses relating to contractor or supplier work, and thus do not know whether circumstances exist that would caution against expanding the two-level enhancement to cover this type of fraud offense. The PAG is likely the appropriate organization to provide comment on this issue.

C. Mitigating Circumstances

The Congressional directive instructs the Sentencing Commission to account for any mitigating circumstances that might justify exceptions to the disaster relief amendments. A defendant's experience as an actual victim of the disaster is a mitigating circumstance that should be included in any amendment. Should the two-level enhancement for disaster related fraud, USSG § 2B1.2(b)(16), be made permanent, we suggest that the Commission recognize that an offender's status as a victim of the disaster is a mitigating factor. The Commission could specify that the § 2B1.1(b)(16) enhancement shall not apply if the defendant has been detrimentally affected by the

¹⁶ 42 U.S.C. § 5122(2).

disaster. Alternatively, the Commission could encourage a downward departure in these circumstances.

D. Conclusion

In summary, we believe that a minimum base offense level is particularly inappropriate for a Guideline that encompasses such a broad range of conduct including the desperate acts of individuals uprooted and traumatized by the disaster itself. Further, inclusion of the administrative costs of recovery as reasonably foreseeable pecuniary harm is unwarranted by the nature of the offense and impractical in application. If anything, the Guideline should be amended to encourage courts to take into account the mitigating circumstances of those who turned to fraud out of desperation after becoming disaster victims themselves.

IV. COURT SECURITY

We agree with the comments of the Practitioners Advisory Group on this topic, as they address our concerns as well.

V. ANIMAL FIGHTING

We agree with the comments of the Practitioners Advisory Group on this topic, as they address our concerns as well.

VI. RULES OF PRACTICE AND PROCEDURE

The Commission also proposes changes to Rules 2.2 and 4.1 of its Rules of Practice and Procedure. Although these rules generally involve Voting Rules for Action by Commission and Promulgation of Amendments, respectively, the proposed changes address only those procedures which govern determinations about whether to give amendments to the guidelines retroactive effect.

We agree with the proposed change to Rule 2.2, which would eliminate the requirement of the affirmative vote of at least three members at a public hearing before staff can be instructed to prepare a retroactivity impact analysis for a proposed amendment. Rule 2.2 should promote, rather than hinder, the initiation of this critical and often time-consuming endeavor and believe the proposed change does just that.

We also agree that Rule 4.1 should be amended to eliminate the requirement that the Commission decide whether to make a proposed amendment retroactive at the same meeting at which it decides to promulgate the amendment, as such an approach is neither practical nor efficient. For example, it would unnecessarily require the preparation of retroactivity impact analyses prior to decisions about whether to promulgate, as such analyses would be needed to inform decision-making and permit meaningful public comment.

We agree with the spirit of the proposed change to Rule 4.1, though the first sentence of the proposed language does not, in our opinion, make sense outside the context of a particular case. We suggest replacing it with the following sentence, which we believe better describes, in the abstract, the import of the proposed amendment:

The Commission, however, shall consider whether to give retroactive application to an amendment that reduces sentencing ranges for a particular offense or category of offenses. See 28 U.S.C. § 994(u); 18 U.S.C. § 3582(c)(2).

This language tracks the statutory language of title 18, section 3582(c) more closely than that of title 28, section 994(u). We believe it conveys a more accurate description of what the Commission does and that citation to both 28 U.S.C. § 994(u) and 18 U.S.C. § 3582(c)(2) is appropriate.

With respect to the Commission's request for comment on whether the Rules of Practice and Procedure should provide a time frame governing final action with respect to retroactive application of an amendment and, if so, what time frame, we do not believe the rules should provide a time frame for final action. We fear that a deadline for final action could impact negatively the ability of the Commission to fully and fairly consider the views of all interested parties, build consensus, and reach a well-considered decision on retroactivity.

In the event the Commission decides a time frame for final action is needed, we suggest a time frame that is more general in nature and that, in any event, does not require final action prior to November 1.

Finally, although the Commission has neither proposed an amendment nor requested comment with respect to Rule 4.3, which governs Notice and Comment on Proposed Amendments, we do believe a change to that rule is needed at this time. Rule 4.3 currently permits the Commission "to promulgate commentary and policy statements, and amendments thereto, without regard to provisions of 28 U.S.C. § 994(x)." Section 994(x) makes the requirements of title 5, section 553 -- publication in the Federal Register and public hearing procedure -- applicable to the promulgation of guidelines.

We strongly believe the Commission should amend Rule 4.3 to require notice and comment with respect to commentary, policy statements and amendments thereto. Issues of great importance which directly impact sentence length in a large number of cases are set forth in policy statements and commentary. Section 1B1.10 is one example, and there are many others, including but not limited to all of Parts H and K of Chapter 5, all of Chapter 6, and the treatment of acquitted and uncharged conduct in § 1B1.3. Moreover, post-*Booker*, the guidelines, commentary and policy statements are all advisory and should be viewed and treated consistently by the Commission. There is no current rationale to allow a change as significant as the one recently made to § 1B1.10 to occur absent notice and comment.

Alternatively, we suggest the Commission amend Rule 4.3 to require publication and public hearing procedure where the commentary, policy statements, and amendments thereto will potentially affect a large number of cases or significantly alter the way a particular guideline will be applied.

Thank you for considering our comments, and please let us know if we can be of any further assistance. We look forward to working with the Commission on these very important issues.

Very truly yours,



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March 21, 2008

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Re: Follow-up on Issues Regarding Proposed Amendments to USSG § 2L1.2
that Arose at March 13 Hearing

Dear Judge Hinojosa:

I write on behalf of the Federal Public and Community Defenders to address issues of concern regarding the proposed amendments to USSG § 2L1.2 that arose at the hearing on March 13.

The Department's witness reiterated the Department's position that it does not advocate an increase in sentences under USSG § 2L1.2 for illegal reentry. She testified that the Department favors Option 3, pointing out that the Commission's data indicates that under Option 3, "overall sentences would remain about the same." But Option 3, like every other option proposed by the Commission for which impact on sentence length could be determined, would result in significantly higher sentences for the least culpable defendants without any reason, with sentences more than doubling for those defendants whose current offense level is 8 or 12.¹ Option 3 also retains categories of offenses that trigger the highest offense levels, contrary to the Department's stated position that the fundamental problem with § 2L1.2 results from the need to engage in a guidelines-level categorical approach. Moreover, the Department supports importing into Option 3 the departure considerations from Option 2, which would encourage increases based on multiple previous removals despite the fact that such increases were virtually never imposed when previously available in the guideline and despite the manifest due process concerns raised by such a provision.

¹ See Memorandum from Kevin Blackwell to USSC Immigration Team, *Impact of Proposed Amendments to §2L1.2(Unlawfully Entering or Remaining in the United States)*, at 12 (Feb. 29, 2008).

In our letter of March 6, we set forth some of the most glaring problems with the options proposed during this amendment cycle.² As much as we support the Commission's efforts to simplify the guidelines, we also recognize that simplification is not a "purpose of sentencing" under 18 U.S.C. § 3553(a)(2) and may actually undermine sentencing purposes and fairness. Any tension between simplification and the SRA's stated goals must be resolved by the Commission's charge under 28 U.S.C. § 991 to establish sentencing policies that, among other things, "assure the meeting of the purposes of sentencing as set forth in [§ 3553(a)(2)]" and "provide certainty and fairness in meeting the purposes of sentencing." See 28 U.S.C. § 991(b)(1)(A)-(B). In other words, in the absence of a sound policy reason based on empirical evidence and national experience that supports an increase in sentences for any category of defendant convicted of illegal reentry on the ground that it furthers the purposes of sentencing, the Commission must refrain from increasing those sentences.

In light of the several bills currently pending before Congress that address immigration issues, we have suggested that the Commission wait before attempting to amend § 2L1.2. Joseph Kohler, Assistant U.S. Attorney from the District of Arizona, argued in response that the Commission should not wait because Congress is unlikely to act in the near future. Mr. Koehler further stated that Option 3 is consistent with S. 2611, the Comprehensive Immigration Reform Act of 2006 passed by the Senate in May 2006. See S. 2611, 109th Cong. § 207 (2006).

However, much like the Department's proposal during the previous amendment cycle, Option 3 is far broader than S. 2611. Unlike S. 2611, Option 3 would (1) apply the greatest enhancements to several categorical offenses without limit on the length of the prior sentence, (2) utilize significantly shorter prior sentence lengths than those specified by section 207 of S. 2611 at each gradation of seriousness, and (3) reduce the number of predicate felonies for the gradation that triggers the highest statutory maximum. Further, unlike S. 2611 or the current § 2L1.2, Option 3 would create a higher penalty level for "national security offenses" and "terrorism offenses" than for any other kind of offense, and then define "terrorism offense" to require a complex factual inquiry far afield of the offense of conviction,³ and "national security offense" as any offense "covered" in Chapter 2, Part M, which includes offenses that bear no resemblance to terrorism with offense levels as low as 6, 13, 14 and 18.

² See Letter from Jon Sands to Hon. Ricardo H. Hinojosa Re: Comments on Proposed Amendments, at 4-8 (Mar. 6, 2008).

³ Under the case law interpreting the same definition in § 3A1.4, the inquiry is: Did the offense of conviction or any relevant conduct of the defendant or others for whose acts or omissions the defendant can be held accountable involve or have as one purpose the intent to promote a Federal crime of terrorism set forth in 18 U.S.C. § 2332b(g)(5), which in turn is defined as an enumerated offense calculated to intimidate, coerce or retaliate against government action? See *United States v. Arnaut*, 431 F.3d 994, 1002 (7th Cir. 2005); *United States v. Mandhai*, 375 F.3d 1243, 1247 (11th Cir. 2004); *United States v. Graham*, 275 F.3d 490, 516 (6th Cir. 2003).

In addition, S. 2611 creates a separate crime where the defendant had been previously removed three or more times, meaning that it must be charged in the indictment and proved beyond a reasonable doubt. In contrast, the Department's proposed changes to Option 3 would not only encourage upward departure based on uncharged conduct that S. 2611 treats as a separate crime, but also based on a preponderance of the evidence that the defendant had been previously removed "multiple" times, which could mean only twice. And unlike Option 3 (or the current § 2L1.2 or any other guideline), S. 2611 specifies that the predicate convictions are elements of the offense of illegal reentry, to be alleged in the indictment and proved beyond a reasonable doubt. Given these many differences, the Department's suggestion that Option 3 best approximates congressional will is without basis.⁴

As we have for many years, the Defenders again noted the absence of any empirical basis or policy reason for the 16-level increase under USSG § 2L1.2(b)(1)(A). In response, Richard Murphy, the Department's Commissioner *Ex Officio*, stated that he was present at the Commission in 1991 and claimed that a study was done before the Commission amended the guideline to include the 16-level enhancement. No such study has ever been published, and the existence of such a study is not supported by historical accounts:

The Commission did no study to determine if such sentences were necessary-or desirable from any penal theory. Indeed, no research supports such a drastic upheaval. No Commission studies recommended such a high level, nor did any other known grounds warrant it. Commissioner Michael Gelacak suggested the 16- level increase and the Commission passed it with relatively little discussion.

Robert J. McWhirter & Jon M. Sands, *A Defense Perspective on Sentencing in Aggravated Felon Re-entry Cases*, 8 Fed. Sent. Rep. 275, 276 (Mar/Apr.1996). See also James P. Fleissner & James A. Shapiro, *Sentencing Illegal Aliens Convicted of Reentry After Deportation: A Proposal for Simplified and Principled Sentencing*, 8 Fed. Sent. Rep. 264, 268 (Mar./Apr.1996) (same). However, if such a study exists, we would very much like to see it so that we can respond accordingly. Otherwise, we must work with the information provided the public, which indicates that the 16-level increase is unsupported by any empirical or policy basis.

We think the Chair's observation that the Commission adopted the 16-level increase because Congress doubled the statutory maximum is a more accurate account than that offered by Commissioner *Ex Officio* Murphy. However, we do not agree with the theory that when Congress increases a statutory maximum, the Commission is required to increase the guideline range to reflect the "kinds of sentences available." The only directive regarding "kinds of sentences available" in the SRA is to the courts, in 18 U.S.C. § 3553(a)(3); there is no such directive to the Commission. Moreover, "kinds of

⁴ For a more thorough discussion of the Department's proposal from the previous amendment cycle, and its inconsistencies with S. 2611 and the identical H.R. 1645, see Letter of Jon Sands to Hon. Ricardo H. Hinojosa Re: Follow-Up on March 20 Hearing, at 2-4 (Mar. 29, 2007).

sentences available" refers to sentence type, not magnitude. *See, e.g.,* 18 U.S.C. § 3553(b)(1) (excised by *Booker*) (distinguishing "kind" from "degree"). Thus, the Supreme Court recently reversed the Eighth Circuit, in part, because although probation was not available under the Guidelines, "§ 3553(a)(3) directs the judge to consider sentences other than imprisonment." *Gall v. United States*, 128 S. Ct. 586, 602 & n.11 (2007). Finally, a congressional increase in the statutory maximum does not obviate the need for empirical evidence showing that a *guideline* increase advances the purposes of sentencing. *See Kimbrough v. United States*, 128 S. Ct. 558, 575 (2007); *Gall*, 128 S. Ct. at 594 n.2.

We would also like to clarify that our purpose in including fast-track dispositions in the rate of below-Guidelines sentences in illegal reentry cases was not to raise the issue of unwarranted disparities between districts based on the presence or absence of fast-track programs, but to urge the Commission to take those sentences into account as a more accurate measure of the appropriate sentence as determined by both the courts and prosecutors. The Commission is charged with receiving, and taking into account, feedback from the courts and the criminal justice community regarding how the guidelines should be improved. *See Rita v. United States*, 127 S. Ct. 2456, 2464-65 (2007); 28 U.S.C. § 994(o). The fact that Congress has sanctioned the use of fast-track programs supports this point rather than undermines it.⁵

Finally, we would like to reiterate that we strongly oppose each of the options proposed by the Commission this amendment cycle for all of the reasons set forth in our letter of March 6, 2008. Most fundamentally, we cannot support Option 1 (or any option) for which the Commission cannot determine its impact on sentences, and the Commission's data indicates that Options 2 and 3 would raise sentences for the least culpable defendants for no reason based in policy or justice. We continue to believe our proposal, modeled on USSG § 2K2.1, represents the most principled starting point, both for purposes of simplification and to assure that USSG § 2L1.2 will better serve the purposes of sentencing.

Thank you for the opportunity to provide these comments, and we look forward to working with you on improving the illegal re-entry guideline.

Very truly yours,



JON M. SANDS
Federal Public Defender
Chair, Federal Defender Sentencing Guidelines
Committee

⁵ We further note that before *Booker* was decided, the Commission itself included fast-track dispositions in the rate of government-sponsored downward departures for illegal reentry cases that were not based on substantial assistance under USSG § 5K1.1. *See, e.g.,* United States Sentencing Commission, 2004 *Sourcebook of Federal Sentencing Statistics*, tbl. 28 (2004).

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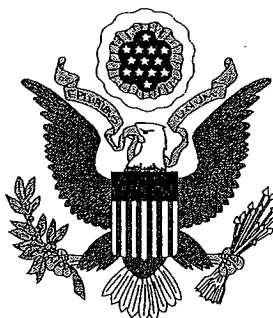
PROBATION OFFICERS ADVISORY GROUP

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March 10, 2008

The Honorable Ricardo H. Hinojosa, Chair
United States Sentencing Commission
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Washington, D.C. 20008-8002

Dear Judge Hinojosa:

The Probation Officers Advisory Group (POAG) met in Washington, DC on February 20 and 21, 2008 to discuss and formulate recommendations to the United States Sentencing Commission. We are submitting comments relating to issues published for comment in January 2008.

Immigration

The group considered the three options and agreed that Option 2 provides ease of application as it moves away from the categorical approach to crimes, which has historically complicated the sentencing process. This approach, which has been supported by the POAG in past position papers, relies on sentence imposed as a measure of seriousness of the offense which is easier to determine than the offense of conviction, due to jurisdictional differences in how crimes are charged and elements contained in the offense of conviction. The group liked the increase in offense level for those defendants who sustained a conviction for another felony offense that was committed subsequent to illegally reentering the United States. Further, the group liked the approach of increasing the base offense level and allowing for a downward adjustment in cases where there are no prior convictions. This is more representative of these types of cases as most have a prior record, those without are the exception.

As to the alternate base offense levels and other adjustments, the group agreed that the highest

levels more closely mirror the existing levels under this guideline. All were in agreement that any option employed should not reduce the existing offense levels for these offenses.

With regard to the reference to offenses described in 8 U.S.C. §1101(a)(43)(A), the group asked that the application notes include a recitation of this section as most districts do not provide a complete Title 8 book and looking for the reference is time consuming.

Finally, consideration of the departure provisions resulted in agreement by all that the upward departure for multiple removals prior to the instant offense should be included under any of the options.

Emergency Disaster Fraud

The group reviewed the recommended SOC and considered the option of including a minimum offense level. The minimum offense level is not recommended unless it differentiates between defendants who were actual victims of the disaster, but received more benefits than that to which they were entitled, and non-victim defendants who exploited the disaster by using the opportunity to seek disaster benefits to which they were not entitled. The group concluded that the 2 level increase is adequate for defendants who were victims of the disaster.

As to other aggravating and mitigating circumstances that might justify additional adjustments, the group expressed concern that the adjustment for number of victims found at §2B1.1(b)(2), as currently defined, may not be employed in disaster relief fraud as the victim is usually *one* agency or relief organization that services many people. Under the current definition of victim, only the agency or organization would be considered a victim. This would not account for cases in which an organization is defrauded of large sums of money or where the defendant collected large sums of money under the pretense of acting on behalf of a charitable organization, thereby diverting funds from the intended victim recipients, who do not meet the definition of "victim" under the guidelines. The group suggested consideration of a special rule similar to the one found in §2B1.1, comment. [n.4(C)(ii)] to account for the multiple victims of the offense. The rule should exclude any defendants who were victims of the disaster and received more relief than that to which they were entitled.

Food and Drug Offenses

Because hGH is used and distributed in a manner consistent with anabolic steroids, and appears to present a harm very similar to steroids, the group agreed that hGH offenses should be addressed under §2D1.1 and treated in the same manner as offenses involving steroids, including the base offense level cap of 20. Further, the group agreed that the SOC's which address steroids specifically, that is, §2D1.1 (b)(7) and (8), should include hGH, and that application note 8 should be modified to include hGH. The group took no position with respect to the unit/milligram equivalency issue and would defer to the judgement of the FDA and other experts with regard to this issue.

It is useful to note that everyone in the group indicated that they rarely, if at all, see cases in their respective districts relating to steroid abuse.

As to the issue for comment regarding the offenses referenced to §2N2.1, the group declined to comment as these offenses tend to be rare and the group has little experience with these types of offenses and this application.

Animal Fighting

The group agreed that a base offense level of 10 and an upward departure for extreme cruelty under §2E3.1 provide the courts with the most latitude in sentencing and adequately addresses the seriousness of the offense.

Court Security Improvement Act of 2007

The POAG reviewed the two new offenses titled under 18 U.S.C. § 1521 and § 119 and would respectfully make the following recommendations regarding implementation under the existing guidelines.

As to 18 U.S.C. § 1521, the group concluded that this offense may be addressed under §2J1.2 (Obstruction of Justice) as this guideline adequately captures the intent and harm caused by this offense. Further, the group suggested that an application note be added to instruct the use of §3A1.2 (Official Victim) for this particular offense.

As to 18 U.S.C. § 119, the POAG considered two existing guidelines for incorporation with this offense, specifically §2H3.1 (Interception of Communications; Eavesdropping; Disclosure of Certain Private or Protected Information) and §2A6.1 (Threatening or Harassing Communications; Hoaxes). The group concluded that §2A6.1 may be the better choice as it captures the intent to threaten or facilitate a crime of violence element of this new offense. Combined with the three level increase for official victim under §3A1.2, this would adequately take into account the aggravating factors of this offense.

The group then considered alternate approaches to application of this guideline relative to this new offense. The first approach includes adding a SOC for a three level increase if the offense of conviction is a violation of 18 U.S.C. § 119, and an application note instructing that an adjustment under §3A1.2 (Official Victim) should not be applied in addition to this SOC. The second option would provide for a base offense level of 15 for defendants convicted of a 119 violation, and no new SOCs. Either alternative provides a 3 level increase for a conviction under this section which might not otherwise apply through §3A1.2, when the victim is a witness, informant, juror, or some other person covered by this statute who may not be considered an official victim.

In addition, the group suggests that a cross reference similar to §2H3.1 would be appropriate insofar as there may be cases in which it can be established that the purpose of the offense was to facilitate another offense, then the guideline for that other offense may be applied if it achieves a higher offense level.

Closing

We trust you will find our comments and suggestions beneficial during your discussions and appreciate the opportunity to provide our perspective on guideline sentencing issues. As always, should you have questions or need clarification, please do not hesitate to contact us.

Respectfully,

2008 Probation Officers Advisory Group



Practitioners Advisory Group

A Standing Advisory Group of the United States Sentencing Commission

March 7, 2008

Honorable Ricardo H. Hinojosa, Chair
United States Sentencing Commission
One Columbus Circle, N.E.
Suite 2-500, South Lobby
Washington, D.C. 20002

RE: Response to Request for Comments on Proposed Amendments for 2008

Dear Judge Hinojosa:

On behalf of the Practitioners Advisory Group, we submit the following comments on the Commission's various proposed amendments and requests for comment for the 2008 amendment cycle. We look forward to addressing some of these proposals at the Commission's hearing, on March 13.

1. EMERGENCY DISASTER FRAUD AMENDMENT

The Commission requests comment on issues related to the recent emergency amendment to § 2B1.1 resulting from the Emergency and Disaster Assistance Fraud Penalty Enhancement Act. The PAG believes that the Commission's recent amendment, as directed by the Act, addresses sufficiently the concerns that prompted the legislation. With one possible exception, further amendments should not be considered until the Commission has accumulated a greater body of experience.

There are three issues for comment. The first is whether the Commission should add a minimum offense level to the new specific offense characteristic for this type of offense. As the guideline now stands, any offense involving fraud or theft in emergency or disaster relief will generate a minimum offense level of 9 (base level of 7 plus the new 2-level enhancement pursuant to § 2B1.1(b)(16)). Within the current Manual, the most closely analogous specific offense characteristic containing a minimum offense level is for fraud involving, *inter alia*, misrepresentations that the defendant was acting on behalf of a charitable organization or government agency. For such conduct, there is a minimum offense level of 10. § 2B1.1(b)(8)(A). A similar floor for the new offense is unnecessary. The difference between a minimum of 9 and a minimum of 10 is too small to warrant an amendment. (Under the enhancement for charitable organization or government agency misrepresentations, an offense level of 8 is possible, so the argument for a floor of 10 in those cases is stronger.) Moreover, with an intended or actual loss of anything greater than \$5,000, the offense level for emergency or disaster relief fraud will be at least 11. U.S.S.G. §§ 2B1.1(a)(1), (b)(1)(C). An amendment affecting the lowest-level cases, where the intended loss is less than \$5,000, is unwarranted.

The second issue is whether the 2-level enhancement should be expanded to fraud or theft involving a benefit paid, etc., in connection with a procurement of property or services related to any emergency or major disaster declaration "as a prime contractor with the United States or as a subcontractor

or supplier on a contract in which there is a prime contract with the United States.” Such an amendment might be warranted. We are aware of no principled basis for treating emergency or disaster relief fraud by contractors or subcontractors in connection with a procurement of property or services different than emergency or disaster relief fraud by others. The addition of this language promotes consistency.

The third request for comment is whether aggravating or mitigating circumstances should be added for disaster fraud cases. Although we agree with the testimony at the Commission’s February 13, 2008 hearing that fraud by victims of disasters or emergencies should warrant a mitigating adjustment, there is much to be said for leaving the recently amendment guideline as is until some experience can be gathered through, among other things, an analysis of sentences imposed under the Act, in particular whether, why and to what extent courts are deviating from the recommended guideline ranges. There is more reason now than when the guidelines were mandatory for the Commission to wait for data before making adjustments that may further complicate the guidelines or otherwise prove ill-advised.

Finally, the PAG understands at least one organization is proposing that § 2B1.1 incorporate language concerning the appropriateness of a lesser sentence (*i.e.*, downward departure) in cases where the defendant was an actual victim of a natural disaster. The PAG supports judicial recognition of instances where the personal consequences of a disaster influenced, and potentially mitigate, a defendant’s offense behavior so as to offset the enhancement required under § 2B1.1(b)(16).

2. HONEST LEADERSHIP AND OPEN GOVERNMENT ACT OF 2007

The PAG has no comment concerning the proposed amendments to § 2C1.1.

3. MISCELLANEOUS FOOD AND DRUG OFFENSES

Human Growth Hormone (hGH)

As a general matter, the PAG supports the previous testimony of Rick Collins, Esquire, of Collins, McDonald & Gann, P.C., particularly with respect to how hGH should be quantified under Guideline 2D1.1. We do not believe that the existing definition of “unit” applicable to trafficking in steroids should be used with distribution offenses involving hGH because hGH offenses present a lesser risk of harm than steroid offenses. As Mr. Collins explained, little scientific evidence supports equal treatment of steroids and hGH for sentencing purposes.

The primary considerations associated with non-medical use of anabolic steroids are not present with non-medical hGH use. For instance, two concerns with anabolic steroids are their psychoactive effects among certain users and the use of excessive amounts beyond what is normally prescribed in lawful medical uses. As Mr. Collins made clear, the medical literature does not support (and Robert Perlstein, M.D. of the FDA does not appear to maintain) that hGH causes enhanced aggression, psychosis, hypomania or other psychological disorders. Nor does the literature suggest that discontinuation of hGH use has any depressive effect on mood. As for abuse of hGH through excessive usage, Mr. Collins testified that while non-medical anabolic steroids users commonly take anywhere from 10-to-100 times the medically prescribed doses, non-medical hGH users typically administer only a fraction of the dosages approved for medical use. Dr. Perlstein appeared to differ on this point, suggesting, as an example, that the typical dosage for a bodybuilder exceeds the typical dose required by adults with severe growth hormone deficiency. Because the evidence on both sides appears somewhat anecdotal, the Commission should

undertake further study concerning how hGH should be treated relative to steroids under the drug quantity table as it bears directly on offense severity.

The Commission also requests comment on whether a maximum base offense level (cap) should apply in § 2D1.1 for hGH distribution offenses. Because hGH presents a lesser harm than anabolic steroids and because questions regarding hGH remain open, the PAG submits that any maximum offense level should be less than the maximum level for anabolic steroids, 20. Moreover, as we submitted previously (*see, e.g.*, 2/30/06 PAG Ltr. re: Proposed Emergency Steroids Amendments at 13), any maximum should be structured so that Category VI offenders have a limited incentive to plead guilty, that is, the possibility of an acceptance of responsibility adjustment that might place their recommended guideline range below the statutory maximum (60 months). Further study of the excessive use issue would undoubtedly also inform decisions regarding a maximum offense level for hGH offenses.

PDMA & FDCA Offenses

The PAG agrees with the separate comments of John R. Fleder, Esquire, and John A. Gilbert, Jr., Esquire, of Hyman, Phelps & McNamara P.C. on the issue of whether § 2N2.1 adequately addresses the numerous statutes currently referenced to that guideline. Messrs. Fleder and Gilbert both recommend that before the Commission takes any action, it should study the issues further, perhaps through a working group similar to that convened in 1994. As the Commission notes in its request for comment, § 2N2.1 covers a wide range of regulatory offenses, including felonies with full knowledge and intent requirements as well as misdemeanors that are virtually strict liability offenses. While the FDA comments raise various theoretical concerns, the empirical support for them is certainly not apparent. Nevertheless, the FDA proposes sweeping changes. This complex, heavily regulated area would benefit greatly from a more systematic study of the available data for sentences imposed under § 2N2.1 to identify areas in need of targeted adjustment due to sentences that have deviated too excessively to one extreme or another.

4. ANIMAL FIGHTING PROHIBITION ENFORCEMENT ACT OF 2007

Through the Animal Fighting Prohibition Act of 2007, Congress increased the penalties for violations of 7 U.S.C. § 2156 from a misdemeanor to a felony, with a three-year maximum term of imprisonment, while also adding a new offense involving the distribution and transportation of instrumentalities associated with bird fighting. 7 U.S.C. § 2156(e). In response, the Commission proposes to move the guidelines provisions concerning § 2156 offense from § 2X5.2 (Class A Misdemeanors) to § 2E3.1 (Gambling Offenses).

The PAG agrees that § 2E3.1 addresses offenses analogous to those covered by the Act in that animal fighting is often associated with gambling. Concurrently, we support the proposed base offense level of 8 and oppose the alternate proposed level of 10. Federal authorities pursued fewer than a half dozen animal fighting cases under the Animal Welfare Act of 1976. H.R. 110-27 (2007). Thus very little data is available by which to assess past sentencing practices. For reasons explained above, the prudent course is to take a less forceful approach, followed by monitoring newly-available sentencing data to determine whether, and to what extent, further adjustments may be warranted.

Proposed Application Note 2 to § 2E3.1 suggests an "upward departure" may be warranted in animal fighting offenses involving extraordinary animal cruelty. The PAG does not oppose sentences above the recommended guideline range in such circumstances. However, the provision appears unnecessary in

that it adds—rather than minimizes—complexity to the Manual. For one, “extraordinary cruelty” is not defined, therein encouraging litigation where it may not be needed to reach an appropriate disposition. *See, e.g., Rep. Steve King Dissenting View in H.R. 110-27* (perspective on treatment of animals informed by one’s background and livelihood). Indeed, consideration of the aggravating circumstance contemplated appears to fall squarely within the ambit of § 3553(a) considerations courts weigh routinely. *See 18 U.S.C. §§ 3553(a)(1), (2)(A)*. To the extent the Application Note remains, the PAG submits that in view of *Gall v. United States*, 552 U.S. ___, 128 S.Ct. 586 (2007) and the prevailing need to move the Manual toward the current state of federal sentencing law, “departure” language should be avoided. Instead, we propose the following:

2. *In the case of an animal fighting offense that involves extraordinary cruelty to an animal, ~~an upward departure~~ a sentence greater than the recommended guideline range may be warranted.*

5. TECHNICAL AMENDMENTS

The PAG has no comment concerning the six proposed technical amendments.

6. CRIMINAL HISTORY

Last year, the criminal history guidelines underwent significant revisions. *See Amendment 709*. Among the changes is that certain prior sentences, such as those imposed on the same day, now count as a single sentence. U.S.S.G. § 4A.1(a)(2). However, where there is an intervening arrest—that is, an arrest for the first offense before the defendant committed the second offense—the prior sentences are always counted separately. *Id.* The Commission now proposes amending § 4A1.2(a) to define “arrest” as including “an attempted service of an arrest warrant where the defendant escapes the arrest or the service of the arrest warrant” and to clarify that “[t]he issuance of a summons or a complaint does not constitute an ‘arrest.’”

The PAG opposes this amendment. To our knowledge, successful escape from an arrest or from the attempted service of an arrest warrant is a rare occurrence in the intervening arrest context. Although the situation no doubt will arise from time to time, we question the propriety of using the amendment process to address infrequently occurring situations, especially where the proposed amendment is contrary to the goal of simplifying the guidelines. In this vein, it is important to recognize that: (a) judges are able to vary from the recommended guidelines sentence to account for this unusual factual scenario and (b) the difference between counting the two prior offenses separately or as a single sentence will rarely be more than one criminal history category.

There are few areas where clarity on particular application questions could not be enhanced through amendments like the one proposed. But, taking the long view, as the Commission must, begs the question whether further clarification on issues that do not arise routinely serves the larger goal of a simplified, stable set of guidelines that are easy for practitioners to understand and for judges to administer. We believe that this goal is undermined by amending the Manual frequently and in a manner that adds complexity. Moreover, by making “escape” part of the definition of arrest—rather than a factor the judge may (but need not) consider—the amendment requires litigation and fact-finding where it may not be needed to reach the appropriate sentence in every applicable case.

Although the other half of the proposed amendment favors defendants by clarifying that issuance of a summons or complaint is not an arrest, for the sake of maintaining simplicity in an area where there are few cases affected by the proposed amendment we believe that the entire amendment should be rejected.

7. **IMMIGRATION**

The PAG has reviewed, and is in agreement with, the reasoned comments of the Federal Public and Community Defenders on this topic. They address fully our perspective and our concerns.

8. **COURT SECURITY IMPROVEMENT ACT OF 2007**

**Appropriate Guideline for Violations of 18 U.S.C. § 1521
(Filing false liens against federal judges and law enforcement officers)**

The Commission has requested comment on the appropriate guideline for violations of 18 U.S.C. § 1521 and suggests two existing guidelines for consideration: § 2J1.2 (Obstruction of Justice) and § 2B1.1 (Theft and Fraud). Use of § 2B1.1 is inappropriate for several reasons.

Guideline section 2B1.1 addresses deprivation of property offenses. In adopting 18 U.S.C. § 1521, Congress was concerned not about federal judges or other federal employees actually losing real or personal property through the filing of a false lien but rather situations where false liens are used to intimidate or harass. Report of the House Committee on the Judiciary, H.R. 110-218 at 16; *see* Stmt. of the Hon. D. Brock Hornby, United States District Judge (D.-Maine) on behalf of the Judicial Conference of the United States to the Senate Committee on the Judiciary (Feb. 14, 2007) at 7-8 ("These liens are usually filed to harass a judge who has presided over a criminal or civil case involving the filer, his family, or his acquaintances").¹ Additionally, § 2B1.1 is loss driven, and determination of loss in false lien cases is problematic (*e.g.*, the cost of having the lien removed, the loss of a potential sale, the value of the property, or some other figure).

Section 2J1.2 is more appropriate because obstruction of justice (or at least an attempt at obstruction) is often at the heart of these forms of intimidation or harassment. Additionally, § 2J1.2 contains several potentially applicable adjustments, including a three-level adjustment if the offense resulted in substantial interference with the administration of justice and a two-level adjustment if the offense involved a substantial number of records or was otherwise extensive in scope. U.S.S.G. § 2J1.2(b)(2), (3).

The Commission might also consider using § 2A6.1 (Threatening or Harassing Communications: Hoaxes) for this offense. The PAG recommends that, if used, a base offense level of six (6) is chosen given that the nature of this offense is far less serious than many other offenses that fall under this guideline. *See, e.g.*, 18 U.S.C. § 871 (Threats Against the President), 18 U.S.C. § 876 (Request for Ransom), 18 U.S.C. § 1992 (False Information Regarding Terrorist Attacks).

It takes some level of sophistication to properly prepare a lien, and false ones are often caught before ever being filed. For example, Chief United States District Judge R. Allan Edgar (E.D.Tenn) reports "one disgruntled litigant had a lien against my home all ready for filing. He got as far as the registrar's

¹ Available at http://judiciary.senate.gov/testimony.cfm?id=2526&wit_id=6071

office, but a court employee prevented him from filing it.” *False Claims Used to Harass Judges*, 34 The Third Branch 8 (August 2002).² In some jurisdictions, state law requires that liens be rejected absent court order to accept them. Therefore, whichever guideline the Commission adopts, we recommend addition of an application note that provides for a sentence below the recommended guideline range where there was no chance that the lien could have successfully been filed. A similar provision was previously included in § 2F1.1, noting that when “a defendant attempted to negotiate an instrument that was so obviously fraudulent that no one would seriously consider honoring it ... a downward departure may be warranted.” U.S.S.G. § 2F1.1, Comment n.11 (1998 ed.).

The PAG recommends against including an application note mandating an official victim adjustment in every case since § 3A1.2 contains adequate instructions to allow for such determinations on a case-by-case basis.

**Appropriate Guidelines for Violation of 18 U.S.C. § 119
(Publishing Restricted Personal Information with Intent to Facilitate Crime of Violence)**

The Commission proposes that § 2H3.1 (Interception of Communication: Eavesdropping; Disclosure of Certain Private or Protected Information) or one of the assault guidelines (§ 2A2.1, *et seq.*) apply to violations of 18 U.S.C. § 119. The PAG recommends against including an application note mandating an official victim adjustment in every case since § 3A1.2 contains adequate instructions to allow for such determinations on a case-by-case basis.

**Potential Enhancements to Guidelines Applying to Violations of 18 U.S.C. § 115
(Threatening Federal Officials)**

Title 18, Section 115 of the United States Code makes it a crime to assault, kidnap, murder, or threaten a federal official, judge or law-enforcement officer and members of their immediate families. Congress has directed the Commission to determine whether an adjustment is warranted when threats made in violation of 18 U.S.C. § 115 are transmitted over the Internet.

Appendix A to the Manual directs that violations of 18 U.S.C. § 115(b)(4), the threat offense, are to be sentenced under § 2A6.1. This section provides a 2-level enhancement if the offense involves more than two threats and a 4-level enhancement for offenses involving substantial disruption of governmental functions. U.S.S.G. §§ 2A6.1(b)(2), (4). Accordingly, the PAG opposes any additional upward adjustments. The realities of modern life make use of the Internet a routine, that is, non-aggravating, occurrence, particularly when compared to other forms of available communication, such as the U.S. Mail. We recognize that the Internet affords the ability to disseminate communications more widely than is possible using traditional communication tools (*e.g.*, “blast” e-mail v. multiple letters) and appreciate that such technology can make it easier to threaten numerous federal officials. However, to the extent that a defendant’s activities in a given case might present as aggravating to such a degree as to potentially warrant a sentence above the recommended guideline range (*e.g.*, a large number of e-mails are distributed simultaneously), courts, which must be presumed to be sensitive to these issues, are free to account for the conduct. *See* 18 U.S.C. §§ 3553(a)(1), (2)(A). In this regard, and consistent with the reasoning stated above, the PAG suggests amending § 2A1.6 by removing Application Note 3, which provides unneeded

² Available at: <http://www.uscourts.gov/ttb/aug02ttb/claims.html>.

complexity to the Manual.

Congress also directed the Commission to consider whether there should also be an adjustment if the sender of such threats was acting in an individual capacity or part of a larger group. There appears no need to include adjustments under individual guidelines. This consideration is adequately addressed under § 3B1.1 (Aggravating Role).

9. RULES OF PRACTICE AND PROCEDURE

The Commission requests comment regarding whether it should amend its Rules and Procedures to provide a specified time frame governing final action with respect to retroactive application of an amendment pursuant to 28 U.S.C. § 994(u), and, if so, what that time frame should be.

The PAG agrees with the Commission that the decision whether to make an amendment retroactive at the same meeting at which the amendment is promulgated may not be practicable in all situations. Accordingly, Rule 4.1 should be amended so as not to *require* retroactivity decisions on promulgated amendments until the Commission has had the opportunity to undertake a complete retroactivity analysis and until interested parties and the public have had the opportunity to comment.

With respect to a time frame under which Commission staff should undertake a retroactivity analysis and under which the Commission should take final action on retroactivity, the PAG believes that the period of time for such analysis and final action should extend no more than six-and-a-half months from promulgation of the final amendment sent to Congress. More specifically, a reasonable period is from May 1 until no later than November 15 of the same year. Any longer period of time, or an unspecified, "general" time period, will create unnecessary uncertainty in the federal criminal justice system as affected parties await final Commission action regarding retroactivity. Furthermore, the proposed period affords ample time to undertake retroactivity analyses as well as to receive comment or testimony. Finally, prolonging an announcement concerning retroactivity after an amendment's effective date creates unwarranted and arbitrary disparities between those offenders receiving the amendment's prospective benefit and those who may benefit retrospectively. The longer the lag between the effective date of an amendment and a later, final action to apply it retroactively only increases such disparities while expanding the pool of litigants who might seek to obtain the benefit of retroactive application.

CONCLUSION

On behalf of our members, who work with the guidelines on a daily basis, we appreciate the opportunity to offer our input on the proposed amendments and issues for comment. We look forward to discussing some of these topics at the hearing on March 13, and we hope that our perspective is useful as the Commission continues to carry out its responsibilities under the Sentencing Reform Act.

Sincerely,

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cc: Hon. Ruben Castillo, Vice Chair
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Commissioner Kelli Ferry
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Judicial Conference of the United States*

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March 11, 2008

Honorable Ricardo H. Hinojosa, Chair
United States Sentencing Commission
One Columbus Circle, N.E.
Suite 2-500, South Lobby
Washington, D.C. 20002-8002

Re: Comments on Proposed Fictitious Liens Amendments

Dear Judge Hinojosa:

I am writing on behalf of the Judicial Conference's Judicial Security Committee, in coordination with the Criminal Law Committee, to convey the views of the two committees while the Sentencing Commission considers sentencing guidelines with respect to the new crimes established under 18 U.S.C. § 1521, criminalizing the knowing filing of false liens against federal judges. For the reasons set forth in the attached statement, the Committees are of the view that classification of the conduct under U.S.S.G. § 2A6.1 is most appropriate.

Although I have provided the statement for the Committees, Judge Henry E. Hudson, Eastern District of Virginia, will testify before the Commission at the hearing on March 13, 2008. Again, the Security Committee is thankful to the Sentencing Commission for taking the Committee's testimony on this important issue.

Sincerely,



Edmund A. Sargus, Jr.

cc: Members Judicial Security Committee
Members Criminal Law Committee

STATEMENT OF JUDGE EDMUND A. SARGUS, JR.
Member, Judicial Security Committee of the Judicial Conference of the United States
United States District Court
Southern District of Ohio
March 10, 2008

Thank you for the opportunity to offer the following comments on behalf of the Judicial Security Committee of the Judicial Conference of the United States. I have coordinated these comments with the chair of the Criminal Law Committee of the Judicial Conference of the United States. The Security Committee appreciates the speed with which the Sentencing Commission has moved to promulgate new Sentencing Guidelines with respect to the new crimes established under 18 U.S.C. § 1521, criminalizing the knowing filing of false liens or encumbrances upon real or personal property owned by federal judges or federal officers and employees in relation to the performance of the official duties of such persons. The offense is punishable by imprisonment not to exceed ten years.

The Sentencing Commission should also take note that according to the U.S. Marshals Service, the number of threats made against federal judges and prosecutors has increased 69 percent from fiscal years 2003 to 2007. In addition, 503 threats were reported in fiscal year 2008, through February 9. Judge Sentelle, chair of the Judicial Security Committee, has noted that "... threats are a significant security concern to his (my) colleagues." Kevin Johnson, *More Judges, Prosecutors at Risk; 69% Increase in Threats Since 2003*, U.S.A. Today, March 6, 2008, at 3A.

The filing of fictitious liens against judicial officers has been a problem for the judiciary for many years. For this reason, in September 1997, the Judicial Conference of the United States agreed to support legislation that would create a new federal criminal offense for harassing or intimidating a federal official, including a judicial officer, with respect to the performance of

official duties to include the filing of a lien on the real or personal property of that official (JCUS-SEP 97, p. 66). Such legislation was repeatedly introduced, but never enacted, in Congress during the following years. In January 2008, however, the Court Security Improvement Act of 2007 was enacted and it included a provision to create a new law for the filing, conspiring to file, or attempting to file any false lien or encumbrance against the property of a federal judge or law enforcement officer because of the performance of that individual's official duties (Public Law No. 110-177, 121 Stat. 2534 (2008)).

These liens are usually filed in an effort to harass judicial officers against whom a civil action has been initiated by the individual filing the lien. Liens are placed on the property of judicial officers based on the allegation that the property is at issue in the lawsuit. Judges are generally very careful about listing their home address in public. When filing the lien, the home address of the judge generally is listed on the filing. By this action alone, the filing individual is saying to the judge in essence, "I know where you live," and could be threatening and intimidating to the judge. While the filing of such liens has occurred in all regions of the country, they are most prevalent in the state of Washington and other western states.

The Administrative Office's Office of General Counsel has had experience with this practice since it acts as a liaison between judicial officers and the Department of Justice to obtain representation for judicial officers sued for actions taken in their official capacities. The General Counsel's Office has observed that the practice of filing liens has been going on for some time. Between September 1992, when the practice began to be recorded, and 2007, liens were filed in at least 81 of the civil cases filed against judicial officers; however, multiple liens were filed in several of these cases. While the incidences of filing liens have occurred in all regions of the

country, they are most prevalent in the western states.

The responsibility to initiate legal action to remove these liens is vested in Assistant United States Attorneys, who represent the judicial officers, and their forms of response vary according to the state law and the circumstances. It is sometimes necessary for the AUSA to bring action in state court for the removal of liens. In some circumstances, an action to remove the liens may be brought in federal court, and in others, state court proceedings are commenced and removed to federal court under the provisions of 28 U. S .C. § 1452. In some cases, the AUSA may seek an injunction against further filing of liens by the litigant. All of these methods are time consuming, of course, but experience indicates that they are ultimately successful.

Nonetheless, the pendency of these liens prior to their removal has caused some judicial officers great inconvenience. In supporting a federal criminal statute, the Criminal Law Committee expressed hope that criminal sanctions might act as a deterrent against false filings. Prior to the enactment of this statute, the Department of Justice was encouraged to prosecute persons filing these liens in state court under state false liens statutes; however, there were problems with this approach.

For one, not all states had laws that were reasonably available for this purpose. A review of state provisions discloses only a handful of applicable specific provisions, and most of these were civil remedies. They permit a party who has had a lien or other encumbrance placed on his or her property for malicious purposes to recover damages, sometimes treble damages, and attorneys fees. A few states have criminal penalties for filing such encumbrances. No state statute that specifically penalizes claims against the property of judicial officers has been found, but Wisconsin has both civil and criminal "slander of title" provisions on the subject.

Wis. Stat. § 706.13 and Wis. Stat. § 943.60, respectively. The civil penalty authorizes punitive damages of \$1,000 plus any actual damages caused by the false failing. The criminal statute is punishable by a fine not exceeding \$10,000 or not more than six years imprisonment. Wis. Stat. § 939.50.

As to the federal judiciary, the core conduct prohibited by § 1521 typically involves the wrongful filing of a lien or encumbrance by a party unwilling to accept a final judgment or sentence. In this context, the filer of the fictitious lien is often engaged in an act of retaliation against a judge, prosecutor, or probation officer. While prompt discovery and subsequent civil litigation may obviate financial harm to parties subject to fictitious liens, the prohibited conduct represents an attack upon the integrity of the judicial system. In the case of an incarcerated filer, or a party with prior criminal involvement in federal court, the conduct indicates that rehabilitation has not occurred. Further, such offender presents a security risk to all parties against whom the fictitious liens have been filed.

I am attaching to my written comments a copy of a decision issued last week in the case of *United States of America v. McCall*, No. C2-06-1051 (S.D. Oh., March 5, 2008). As the opinion describes, Bondary McCall is serving a sentence of 292 months in the federal prison system. From May of 2005 through November of 2006, Bondary McCall filed a series of fictitious claims against me, as well as an Assistant United States Attorney. In November of 2006, McCall attempted to file a U.C.C. financing statement listing me as indebted to him in the amount of \$19 million.

Due in part to the fact that I reside in a small, rural community, the filings were recognized as suspicious and sent to the county prosecutor. Shortly thereafter, the United States

Attorney's Office instituted a lawsuit seeking to restrain McCall. I draw your attention to the fact that, in many states, official record keepers – clerks of court, county recorders – are not authorized to screen documents or refuse filings so long as technical requirements are met and proper fees are tendered. This consideration presents a concern that a fictitious lien will be recorded without notice to a judicial officer. As a further example of these concerns, on March 7, 2006, McCall did in fact cause a fictitious lien to be filed in the office of the Washington Secretary of State. Fortunately, the U.C.C. filing lists the AUSA and me as the secured party, rather than the debtor.

The gravity of the offense is not confined to the potential financial harm or inconvenience to a judge. The offense involves conduct which reveals a deep antagonism against the legal system and demonstrates that the perpetrator will not be restrained from unlawful conduct. The Security Committee considered, and rejected, two possible guideline analogues the Sentencing Committee might consider, including obstruction of justice and fraud. Specifically, that although the Sentencing Commission could also consider the use of U.S.S.G. § 2J1.2, Obstruction of Justice, the Security Committee believes that a substantial number of fictitious liens involving judges have been filed after the conclusion of litigation. Such filings were not intended to actually obstruct judicial proceedings, but to instead extract retaliation or vengeance upon a judicial officer. Because the filing of fictitious liens is not necessarily addressed to pending cases, the nexus between the filing and the alleged obstruction may be lacking.

Similarly, in the Security Committee's view, U.S.S.G. § 2B1.1, which addresses fraud and related financial crimes, would not capture the essence of the offense. The Security

Committee believes that the gravamen of the fictitious-lien offense is the threat to the legal process, not to the financial security of a judge, prosecutor or probation officer. The wrongfully filed liens will ultimately be removed through legal proceedings, if necessary. In most instances, there will not be actual economic harm. The filing of fictitious liens, however, clearly indicates that the perpetrator is a threat to the legal process and to a particular jurist.

In light of these concerns, the Security Committee is of the view that classification of the conduct under U.S.S.G. § 2A6.1 is most appropriate. This Guideline currently applies in cases involving threatening or harassing communications. While the base offense level is 12, several specific offense characteristics relevant to § 1521 increase the offense level. For example, § 2A6.1(3) provides for a 3 level increase, if the offense involves violation of a court order. It is likely that a civil action seeking injunctive relief banning a defendant from sending harassing mail from a penal institution may precede the filing of criminal charges. Consequently, a later fictitious-lien filing also violates the earlier injunction and should warrant an increased sentencing guideline range.

The Security Committee is also of the view that the offense level should increase if the defendant has filed multiple fictitious liens. Likewise, the offense level should increase if the conduct causes substantial economic harm or extended litigation to remove the fictitious lien from public records. Finally, because U.S.S.G. § 2A6.1 covers more than fictitious-lien filings against judges, prosecutors and probation officers, the Security Committee believes that a Chapter Three Adjustment, involving official victims, is warranted under U.S.S.G. § 3A1.2.

Again, thank you for the opportunity to share the views of the Security Committee of the Judicial Conference with you as you consider this important issue.

**UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF OHIO
EASTERN DIVISION**

United States of America

Plaintiff,

v.

Case No. 2:06-cv-01051

Bondary McCall,

Judge Michael H. Watson

Defendant.

OPINION AND ORDER

Plaintiff the United States of America seeks declaratory and injunctive relief against Defendant Bondary McCall. Plaintiff alleges Defendant has filed and continues to file harassing and frivolous documents against various federal officials in retaliation for prior criminal proceedings against the Defendant. Plaintiff seeks a judgment permanently enjoining Defendant from filing documents with government agencies without first obtaining written leave of this Court. Furthermore, Plaintiff requests a judgment declaring any such documents currently filed or filed in the future without leave of this Court to be void and of no legal effect. For the reasons that follow, the Court grants Plaintiff's motion for summary judgment.

I. FACTS

A. Parties

Plaintiff is the United States of America ("United States"). Defendant, Bondary McCall, is an inmate (federal register number 43827019) confined in federal custody at the Federal Correctional Institution in Williamsburg, South Carolina.

B. Case History

Plaintiff filed the original complaint on December 14, 2006. Plaintiff filed a Motion for Summary Judgment on January 9, 2007. On March 7, 2007, the Court issued an order granting Defendant fourteen days to respond to the pending motion for summary judgment. Defendant did not respond. On March 23, 2007, Plaintiff filed a Supplemental Memorandum Supporting Motion for Summary Judgment. On September 21, 2007, Defendant filed a Response to Plaintiff's Supplemental Motion for Summary Judgment.

Where, as here, a motion for summary judgment goes unopposed, a district court properly relies upon the facts provided by the moving party. *Guarino v. Brookfield Township Trs.*, 980 F.2d 399, 404-405 (6th Cir. 1992).

C. Defendant's Filings

In December 1994, Defendant was sentenced to 292 months imprisonment for an unrelated offense. Since his sentencing, Defendant has filed over twenty collateral actions and appeals. Each of these cases, naming local and federal officials as defendants, was dismissed by the respective courts.

Subsequent to his incarceration, Defendant has filed numerous documents

alleging a variety of financial claims against various federal officials. Many of these documents allege financial claims against the Hon. Edmund A. Sargus, Jr. ("Judge Sargus"), a United States District Judge in the Southern District of Ohio, and Robyn Jones Hahnert ("Hahnert"), an Assistant United States Attorney for the Southern District of Ohio.

In May 2005, Defendant conveyed a document to the Internal Revenue Service (IRS) in Washington, D.C. entitled "Reporting of Tax Delinquents". The document identified Judge Sargus and Hahnert as "Tax Fugitives".

In June 2005, Defendant sent the United States Department of Justice, via U.S. Mail, a "notice of tort claim" against the United States, in the amount of \$19,920,000,000.00, for damages allegedly caused by Judge Sargus, Hahnert and others.

In June 2005, Defendant named Judge Sargus, Hahnert, and others, in a document titled "Affidavit Notice of Default" filed with the United States District Court for the Southern District of Ohio.

In October 2006, Defendant sent to Belmont County, Ohio officials, via U.S. Mail, a document titled "UCC Financing Statement" listing Judge Sargus as the "Debtor" and Defendant as the "Secured Party". The document purported to encumber "all of Debtor's assets, land, and personal property"

In November 2006, Defendant sent to the Belmont County, Ohio Treasurer, via U.S. Mail, a letter requesting the Treasurer provide tax assessments for Judge Sargus, provide all parcel numbers Judge Sargus is paying taxes on, and list Defendant on the county records.

In November 2006, Defendant sent to Judge Sargus, via U.S. Mail, a letter identifying Judge Sargus as "Debtor Judgment" and claiming to possess a "Security Interest" in Judge Sargus.

Neither Judge Sargus or Hahnert are indebted to Defendant and neither have ever had a commercial relationship with Defendant. There is no valid security agreement between Defendant and the federal officials. There are no judgments entered against either Judge Sargus or Hahnert involving Defendant that would justify the filing by Defendant of any lien, financing statement, or other filing concerning the federal officials' property.

Plaintiff filed this complaint on Dec. 14, 2006. Plaintiff seeks a declaratory judgment that the purported "liens" and or financing statements prepared, attempted to be filed, or filed by Defendant are null, void, and of no legal effect and that Defendant had no factual or legal basis to file such financing statements. Plaintiff also seeks to permanently enjoin Defendant from filing or attempting to file any document claiming financial interests against any federal officer or employee without leave of this Court.

II. SUMMARY JUDGMENT

The standard governing summary judgment is set forth in Fed. R. Civ. P. 56(c), which provides:

The judgment sought shall be rendered forthwith if the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to judgment as a matter of law.

Summary judgment will not lie if the dispute about a material fact is genuine; "that is, if the evidence is such that a reasonable jury could return a verdict for the nonmoving

party." *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986). Summary judgment is appropriate, however, if the opposing party fails to make a showing sufficient to establish the existence of an element essential to that party's case and on which that party will bear the burden of proof at trial. *Celotex Corp. v. Catrett*, 477 U.S. 317, 322 (1986); see also *Matsushita Electric Industrial Co., Ltd. v. Zenith Radio Corp.*, 475 U.S. 574, 588 (1986).

III. DISCUSSION

A. Declaratory Relief

Plaintiff requests a declaratory judgment that the purported "liens" and/or financing statements prepared, attempted to be filed, or filed by Defendant are null, void and of no legal effect and that Defendant had no factual or legal basis to file such financing statements. Given the uncontested facts offered by the Plaintiff, the Defendant's pseudo-financial filings are without merit. The Defendant has demonstrated no contractual relationship with any federal employee and consequently has no property claim against any of the named individuals. This Court declares the Defendant's purported "liens" and/or financing statements to be void and of no legal effect.

B. Injunctive Relief

Plaintiff asks this Court to permanently enjoin the Defendant from filing liens, UCC statements or other documents with government agencies without leave of this Court. Plaintiff alleges the case at bar satisfies the four requirements for permanent injunctive relief as described by the Eastern District of Texas in *Moore v. City of Van*,

Texas. 238 F.Supp.2d 837, 852 (E.D. Tex. 2003). Because this Court agrees, the Defendant is hereby permanently enjoined from filing liens, UCC statements or other documents with governmental agencies without leave of this Court.

While *Moore* is not mandatory authority for this Court, it is instructive to the extent it is a refined version of this Court's discussion of the requirements for permanent injunctive relief in *Dayton Christian Schools v. Ohio Civil Rights Com'n*. 578 F.Supp. 1004 (S.D. Ohio 1984) (*rev'd on other grounds*, 766 F.2d 932 (6th Cir. 1985), *rev'd and remanded on other grounds*, 477 U.S. 619 (1986)). In *Dayton*, this Court explained that permanent injunctive relief is appropriate when the plaintiff has actually prevailed on the merits of his claim, has demonstrated requisite real and present danger of irreparable injury, and the balancing of equities between the parties weighs in favor of an injunction. The factors are similar to those considered when determining whether a preliminary injunction should be issued. "Specifically, the Court must consider whether the plaintiff has demonstrated irreparable injury, whether the issuance of the injunction 'would cause substantial harm to others,' and 'whether the public interest would be served by issuing' an injunction." *Id.* at 1017 (quoting *Friendship Materials, Inc. V. Michigan Brick, Inc.*, 679 F.2d 100 (6th Cir. 1982)).

In *Moore* the Eastern District of Texas neatly clarified the requirements for permanent injunction. "The standard for permanent injunction is 'essentially the same' as for a preliminary injunction, in that the plaintiff must establish each of the following four elements: (1) actual success on the merits; (2) a substantial threat that failure to grant the injunction will result in irreparable injury; (3) that the threatened injury

outweighs any damage that the injunction may cause the defendants; and (4) that the injunction will not impair the public interest." *Moore*, 238 F.Supp.2d at 852. The difference between the standard for a permanent injunction and a preliminary injunction is that a permanent injunction requires the court to determine the plaintiff's actual success on the merits rather than the plaintiff's likelihood of success.

A permanent injunction cannot be granted without careful consideration by the court. The Sixth Circuit quoted Professor Wright in discussing the "ordinary principles of equity" that must be considered prior to issuing a permanent injunction. "There is no power the exercise of which is more delicate, which requires greater caution, deliberation, and sound discretion, or more dangerous in a doubtful case, than the issuing an injunction; it is the strong arm of equity, that never ought to be extended unless to cases of great injury, where the courts of law cannot afford an adequate or commensurate remedy in damages." *Detroit Newspaper Publishers Ass'n v. Detroit Typographical Union No.*, 471 F.2d 872, 876 (6th Cir. 1972) (quoting 3 Barron & Holtzoff, *Federal Practice and Procedure* (Wright Ed.) § 1431). So it is with careful deliberation that this Court evaluates the applicability of a permanent injunction to the case at bar.

1. Plaintiff's Success on the Merits

To win a permanent injunction the Plaintiff must demonstrate actual success on the merits of the case. The Defendant here has filed numerous frivolous documents alleging a variety of financial claims against various federal officials. The undisputed facts demonstrate the Defendant has no legitimate financial claim against any of the

federal officials named in the various filings. In particular, Defendant's October 2006 UCC Financing Statement attempting to encumber the assets of Judge Sargus amounts to fraud. Judge Sargus has no contractual relationship with the Defendant to warrant Defendant's claim to Judge Sargus' assets.

There can be no genuine issue of material fact as to the invalidity of Defendant's filings. The Plaintiff's success on the merits is established.

2. Substantial Threat of Irreparable Injury

Injunctive relief is appropriate only where there exists a substantial threat that failure to grant the injunction will result in irreparable harm. Here, this threshold is satisfied. Defendant's frivolous filings place a constant and irreparable strain on federal employees and the federal offices they serve. By Defendant's own admission ("I have 14 more year (sic) to study, study and study,") he intends to continue his malicious filing campaign. To allow the Defendant to persist would impose a constant burden on the victims of his unwarranted financial filings.

The Supreme Court of North Dakota recognized the problem in a similar situation. "A strong and stable corrections system is necessary to protect the general welfare of the people. We cannot allow that system to be undermined by permitting an inmate to indiscriminately file liens not authorized by law against the property of . . . employees." *State v. Jensen*, 331 N.W.2d 42, 47 (N.D. 1983). In that case, an inmate was permanently enjoined from filing illegitimate, unauthorized liens against state employees. The court explained "[a]ny purported lien filed by [the inmate] would encumber the property of the State employee against whom the lien was filed and effectively inhibit the alienability of that property . . . this unwarranted cloud on the title

could result in damages which would be difficult to ascertain and could cause irreparable harm to the State employee." *Id.*

The Defendant's fraudulent filings are a legitimate concern for federal employees. The Plaintiff appropriately notes the irreparable negative effect such filings might have on a victim's credit score or other financial interests. Because the Defendant has imposed a real harm and apparently wishes to continue to do so, his actions demonstrate a substantial threat of continuing and irreparable injury.

3. Injury Outweighs Damage Caused by Injunction

Injunctive relief is only to be granted if the injury to the Plaintiff outweighs the damage the injunction would cause the Defendant. Here, a balancing of the relative hardships weighs in favor of injunctive relief. A permanent injunction will protect federal officials from the injury described above, but will still enable the Defendant to file public records pending court approval. While the Defendant's ability to file public documents might arguably be delayed, his ability to obtain court approval provides him with a legitimate mechanism to file valid documents.

4. Public Interest

Injunctive relief may only be granted if the injunction will not impair the public interest. In the case at bar, injunctive relief will in fact advance the public interest. Public officials, and the offices they serve, should be protected from frivolous filing campaigns such as this. Further, our nation's financial institutions cannot fall victim to the Defendant's personal vendettas. Left unchecked, the Defendant's illegitimate financial claims would inevitably affect someone's legitimate financial interests. It is in

the public's best interest that Defendant be barred from future filings pending the approval of the court.

IV. DISPOSITION

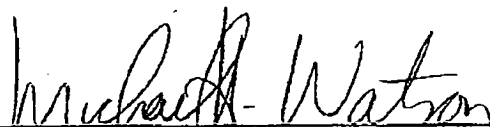
Based on the foregoing analysis, the Court **GRANTS** Plaintiff's summary judgment motion (Doc. 6). Moreover, the Court **GRANTS** Plaintiff's request for permanent injunctive relief.

The Clerk shall enter a final judgment on the merits in this case in favor of Plaintiff, and against Defendant, as follows:

1. The Court **DECLARES** the Defendant's purported "liens" and/or financing statements filed against federal officials, including Judge Sargus and Robyn Hahnert, to be void and of no legal effect; and
2. Defendant is hereby **PERMANENTLY ENJOINED** from filing liens, UCC statements or other documents with governmental agencies without first seeking and obtaining written leave of this Court.

The Court further warns Defendant that Congress recently passed into law a provision criminalizing the filing of false liens against federal judges and federal law enforcement officers. Court Security Improvement Act of 2007, Pub. L. No. 110-177, 121 Stat. 2534 (2008). Violations are punishable by fine and/or up to ten years imprisonment. *Id.*

IT IS SO ORDERED.


MICHAEL H. WATSON, JUDGE
UNITED STATES DISTRICT COURT



March 28, 2008

United States Sentencing Commission
Attn: Public Affairs
One Columbus Circle, N.E.
Suite 2-500
Washington D.C. 20002-8002

**Re: Comments Concerning January 28, 2008 Federal Register Notice
Regarding Miscellaneous Food and Drug Offenses**

INTRODUCTION

The Pharmaceutical Research and Manufacturers of America ("PhRMA") is pleased to submit these comments in response to the United States Sentencing Commission's January 28, 2008 Federal Register Notice ("Notice") regarding possible amendments to the Sentencing Guidelines concerning miscellaneous food and drug offenses. 73 Fed. Reg. 4931-35 (2008). PhRMA is a voluntary, nonprofit association that represents the country's leading pharmaceutical research and biotechnology companies, which are devoted to inventing medicines that allow patients to live longer, healthier, and more productive lives. Member companies are leading the way in the search for new cures. In the past decade alone, PhRMA members invested approximately \$300 billion to develop new medicines. See PhRMA, *Pharmaceutical Industry Profile 2007* at 42 (2007).

The Notice proposes a number of amendments with regard to Federal Food, Drug, and Cosmetic Act (FDC Act) offenses. Many of these proposals relate to the sentencing of human growth hormone (hGH) offenses. In addition, the Commission has requested comments regarding a few other FDC Act matters, including whether it should alter Guideline 2N2.1 if it does not adequately address the statutes referenced in that Guideline, such as the FDC Act.

SUMMARY OF PhRMA'S POSITIONS

In general, PhRMA supports a rigorous sentencing scheme whereby the government can help protect the public health and safety by employing, when appropriate, criminal sanctions against persons found to have violated the FDC Act. We believe that, with one exception discussed below, Sentencing Guideline 2N2.1 does not require revision at this time, based on the available evidence. Indeed, to the best of our knowledge, not a single federal court has expressed concern about this Guideline in any case. Should the Commission deem further action is warranted, PhRMA supports the

Pharmaceutical Research and Manufacturers of America

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formation of a working group to study these issues and to make recommendations to the Commission that are supported by a reasoned basis for any suggested revisions. Finally, we suggest, consistent with prior FDA recommendations, that the Commission take this opportunity to strengthen the Guidelines as they relate to pharmaceutical counterfeiting offenses.

I. PHARMACEUTICAL COUNTERFEITING SENTENCES SHOULD BE SIGNIFICANTLY INCREASED

Consistent with prior recommendations of the Food and Drug Administration (FDA) and given the increasing public health risk posed by counterfeit pharmaceuticals, PhRMA believes that criminal sentences for counterfeiting should be significantly increased. *See* Combating Counterfeit Drugs, A Report of the Food and Drug Administration, February 2004, at iii, 18-19. Sentences should be sufficient to deter counterfeiting activities, particularly by organized crime.¹ As recognized by Congress² and FDA, counterfeit drugs pose a significant risk to the public health and safety.³ In

¹ While PhRMA believes that the vast majority of counterfeit drug convictions are currently sentenced under the § 2B1.1 Guideline, there are misdemeanor convictions – whether by plea or following a trial -- which are possible candidates for sentencing under Guideline 2N2.1. Accordingly, we believe an amendment to § 2N2.1 is appropriate for drug counterfeiting cases. *See, e.g.*, FDA's July 27, 2004 letter to the Commission at 5-6 (discussing the need for increased penalties under § 2N2.1 in a hypothetical case involving "a wholesale distributor who sells counterfeit . . . prescription drugs but claims not to have known . . .").

² *See, e.g.*, 21 U.S.C. § 355e(c) ("The Secretary shall expand and enhance the resources and facilities of agency components of the Food and Drug Administration involved with regulatory and criminal enforcement of this chapter to secure the drug supply chain against counterfeit . . . drugs . . . from domestic and foreign sources."); *see also* Feb. 13, 2008 Statement of FDA Associate Commissioner William McConagha at 8.

³ *See* FDA August 22, 2007 letter to the Commission at 2 (discussing the risk to public health from counterfeit drugs in connection with the Prescription Drug Marketing Act); FDA July 27, 2004 letter at 2 ("For example, their blood pressure or cholesterol may not be controlled or their depression may not be treated because their medications are counterfeit."); Statement of William McConagha at 13 ("Congress was also concerned with the distribution of . . . counterfeit drugs to American consumers. Defendants who introduce drugs in these categories into the prescription drug distribution system create a heightened health risk above and beyond defendants who distribute otherwise legitimate FDA-approved drug products in violation of the [FDC Act]. Therefore, FDA believes that enhancement for the distribution of . . . counterfeit drugs is appropriate."); FDA August 29, 2006 letter to the Commission at 1 (same).

fact, worldwide counterfeit drug sales are estimated to reach \$75 billion by 2010.⁴ PhRMA agrees with FDA that the serious public health risks posed by counterfeit drugs warrant tougher criminal penalties. In the Final Report of the FDA's Counterfeit Drug Task Force, the Agency noted that: "[t]here was overwhelming support and unanimous agreement [in the public comments] that higher penalties for counterfeiting are needed" to deter drug counterfeiters. *See Combating Counterfeit Drugs, A Report of the Food and Drug Administration* 19 (2004). FDA further noted that:

Current sentencing guidelines for counterfeit drug distribution are not commensurate with the public health threat posed by this criminal activity and strengthening the guidelines should help deter such conduct in the first instance. Despite the significant threat to public health posed by counterfeit drug products, current law provides penalties far below the level of some purely economic crimes. For example, counterfeiting a prescription drug label (bearing a registered trademark) is punishable by up to ten years in prison, while counterfeiting the drug itself is punishable by a maximum of only three years in prison. Therefore, FDA plans to continue to pursue its request that the United States Sentencing Commission consider amending the sentencing guidelines to substantially increase criminal penalties for manufacturing and distributing counterfeit drug products and to specifically provide for enhanced penalties based on the level of risk to the public health involved in the offense.

Id.

While PhRMA appreciates the increased attention and resources that FDA has devoted to pharmaceutical counterfeiting in the early 2000s,⁵ we believe more can and should be done in this area, particularly because FDA cannot commit unlimited resources to counterfeiting cases. Based on a limited review of publicly available FDA reports on sentences imposed following criminal convictions in drug counterfeiting cases, and acknowledging that PhRMA does not know the particulars of the cases referenced below, we submit that the sentences imposed in these cases do not appear to reflect the seriousness of the public health threat posed by counterfeit drugs. A few examples appear below:

1. In March 2005, a defendant who admitted that he conspired to import thousands of counterfeit prescription drug tablets into the United

⁴ WHO Fact Sheet No. 275, Nov. 14, 2006, *available at*:
<http://www.who.int/mediacentre/factsheets/fs275/en/index.html>.

⁵ <http://www.fda.gov/oc/initiatives/counterfeit/update2005.html> (showing that FDA increased the number of counterfeit cases it opened in a year from six (6) in 2000, to fifty-eight (58) in 2004).

States was sentenced to 18 months in prison, followed by 3 years probation, and was fined \$6,000.⁶

2. In a case involving a counterfeit birth control patch with no active ingredient, Robert Lawrence was sentenced in February 2006, to 24 months probation and ordered to forfeit \$75,000 in assets. The defendant grossed approximately \$25 million per year from the criminal scheme.⁷

3. In September 2004, Louis Urbina was sentenced to 10 months incarceration and 1 year probation in a case involving counterfeiting two prescription drugs.⁸

4. In October 2004, an Alabama drug wholesaler was sentenced to 5 years probation and fined \$24,000 in connection with its conviction for selling counterfeit drugs.⁹

Based on the serious public health risks posed by counterfeit drugs, PhRMA recommends that the Commission adopt the following three amendments to the Sentencing Guidelines as soon as possible:

I. Add at the end of 2N2.1(a) the following:

“If the offense concerned a violation of 21 U.S.C. § 331(i) (relating to counterfeit drugs), or any other offense relating to counterfeit drugs, increase the base offense level by six (6) levels.”

II. Under the “Cross References” in 2N2.1 add the following:

“(3) If the offense concerned counterfeit goods, apply § 2B5.3 (Criminal Infringement of Copyright or Trademark) if the resulting offense level is greater than that determined above.”

⁶ FDA, COMBATING COUNTERFEIT DRUGS: A REPORT OF THE FOOD AND DRUG ADMINISTRATION ANNUAL UPDATE (2005), <http://www.fda.gov/oc/initiatives/counterfeit/update2005.html>.

⁷ 2006 FDA ENFORCEMENT STORY 6-13, http://www.fda.gov/ora/about/enf_story/ch6/default.pdf.

⁸ 2004 FDA ENFORCEMENT STORY, Office of Criminal Investigations 21, http://www.fda.gov/ora/about/enf_story2004_archive/ch6/default.pdf.

⁹ 2004 FDA ENFORCEMENT STORY, Office of Criminal Investigations 28, http://www.fda.gov/ora/about/enf_story2004_archive/ch6/default.pdf.

III. Under 2B5.3(b)(5) concerning Specific Offense Characteristics, amend that subsection to read as follows:

“(5) If the offense involved (A) the conscious or reckless risk of serious bodily injury; or (B) possession of a dangerous weapon (including a firearm); or (C) trafficking in counterfeit drugs in connection with the offense, increase by 2 levels. If the resulting offense level is less than level 13, increase to level 13.”

We believe that the changes listed above reflect the seriousness of pharmaceutical counterfeiting offenses. *See* 18 U.S.C. § 3553(a)(2)(A). Moreover, because counterfeiters are not acting as legitimate companies concerned with FDA regulatory oversight, these increased penalties are necessary to help deter drug counterfeiting. *Id.* at § 3553(a)(2)(B). Increased penalties may also help to protect the public health from further counterfeiting crimes. *Id.* at § 3553(a)(2)(C).

II. GUIDELINE 2N2.1 DOES NOT OTHERWISE REQUIRE REVISION

Aside from the applicability of the Guidelines to pharmaceutical counterfeiting, there does not appear to be any evidence presented to the Commission that the existing system for sentencing FDC Act offenses is inadequate or deficient. Although we are not commenting on the specific amendments to the 2N2.1 Guideline that the Commission recently proposed (such as for hGH offenses), it is unclear from the public record whether wholesale changes to 2N2.1 as set forth in the Commission’s Notice (73 Fed. Reg. at 4935, first column at numbered paragraph 5) are necessary or appropriate. Our conclusion is grounded on the FDC Act statutory scheme, the current wording and purposes of the Guidelines, and the actual record of FDC Act criminal enforcement. Moreover, we agree with FDA Associate Commissioner McConagha regarding “the magnitude and complexity of reforming this section.” Statement of William McConagha at 15.

A. Misdemeanor Offenses, the Park Doctrine and Strict Liability

PhRMA believes that intentional violations of our public health statutes should be punished appropriately. At the outset, it is important to recognize that any potential amendments to Guideline 2N2.1 would *not* relate to those persons who are convicted of intentionally flaunting the public health and safety by engaging in fraudulent conduct. Under the 2N2.1 Guideline, if an offense involves fraud, Guideline 2B1.1 would apply. The overwhelming majority of FDC Act cases prosecuted in federal courts are felony cases, where a defendant is accused of having violated the FDC Act “with the intent to defraud or mislead”—and thus the fraud guideline applies, not the 2N2.1 Guideline.

In contrast, cases sentenced using Guideline 2N2.1 cases are strict liability regulatory offenses, for which the U.S. Supreme Court has established a very low bar for

the Government to meet in order to prove its case. See *United States v. Park*, 421 U.S. 658 (1975). In *Park*, the Supreme Court upheld misdemeanor convictions based on the premise that responsible persons who manage FDC Act-regulated businesses have an affirmative duty to insure that the products they sell are safe. Therefore, a person responsible for FDC Act compliance by virtue of his or her position in a company can be convicted of a criminal misdemeanor, even though he or she did not personally engage in, or even know about, illegal activity. The Court stated that the FDC Act punishes neglect where the law requires care or inaction, and imposes a positive duty to seek out and remedy violations when they occur, and also a duty to implement measures that will insure that violations will not occur.

As a result, the “*Park* doctrine” places a substantial amount of discretion in the hands of a prosecutor, because an FDC Act violation committed by a company can lead to strict criminal liability for corporate officers and others. Indeed, the Department of Justice has published a model jury instruction on charging FDC Act misdemeanors consistent with this doctrine.¹⁰ Thus, officers with responsibility and authority in a food, drug, or medical device manufacturer could face a criminal charge any time there is a single FDC Act violation in one of their company facilities, even if they do not have actual knowledge of the complex regulatory requirements enforced by FDA or the activity in question.

Because of the wide breadth of the FDC Act’s criminal sanctions, which apply to “no intent” offenses of the FDC Act, it is particularly important that the Commission should not increase the sentences for these types of violations unless there is a clear record that the existing sentencing scheme is not working. We are not aware that this record has been presented in any public forum.¹¹ Moreover, as will be discussed below, courts have sufficient mechanisms at their disposal to allow them to appropriately punish violations of the FDC Act.

B. Existing Sentencing and Other Mechanisms Can Increase FDC Act Sentences and Otherwise Deter Violations

Without altering Guideline 2N2.1, there are already sentencing mechanisms in place to increase an FDC Act sentence when the facts so warrant. As the Commission knows, between the Chapter 3 Adjustments, and the Chapter 5 grounds for departure, the existing Guidelines contain a number of bases upon which a court can generally fashion a

¹⁰ United States Attorneys' Manual, Title 4, Civil Resource Manual No. 105, available at http://www.usdoj.gov/usao/eousa/foia_reading_room/usam/title4/civ00105.htm.

¹¹ By contrast, because pharmaceutical counterfeiting presents a documented and emerging risk to public health and safety, for the reasons discussed in footnote 1 *supra*, we believe special treatment of such activities under § 2N2.1 is warranted.

sentence appropriate to the particular facts and circumstances. *See, e.g.*, § 3B1.1 (Aggravating Role); § 3B1.3 (Abuse of Position of Trust or Use of Special Skill) § 5K2.1 (Death); § 5K2.2 (Physical Injury); § 5K2.7 (Disruption of Governmental Function); and § 5K2.14 (Public Welfare). These adjustments and departures apply to 2N2.1 cases.

For legitimate pharmaceutical manufacturers, FDA's inspection observations, warning letters, and other administrative actions by FDA are taken extremely seriously. Civil litigation by the Department of Justice on behalf of FDA (whether seizure of particular products, or an injunction against further manufacturing or distribution) can have disastrous consequences. A criminal investigation – let alone charges or a conviction – often has even more significant detrimental consequences. Thus, PhRMA does not accept an assertion that the existing Guidelines are too lenient, particularly when one considers the range of enforcement tools available to FDA that can be taken in conjunction with a criminal prosecution.

Moreover, the vast majority of criminal FDC Act cases do not arise in a vacuum. There is frequently a civil component to the government's enforcement (often under the False Claims Act), and the persons and entities being investigated by FDA may also be subject to administrative remedies, including but not limited to exclusion and debarment. An assessment of the adequacy of the existing Guidelines must recognize this regulatory environment. *See* 18 U.S.C. § 3553(a) (sentence should be "sufficient but not greater than necessary" to comply with sentencing goals).

Therefore, based on the available evidence, the 2N2.1 Guideline, supplemented by other relevant existing Guidelines, adequately provides judges with the necessary authority and flexibility to impose a serious sentence when warranted, and deter most persons from violating the FDC Act. Indeed, we are not aware of a single case (and FDA's letters to the Commission do not cite one) where a judge regarded the existing 2N2.1 Guideline as a barrier to an appropriate sentence.

CONCLUSION

PhRMA supports FDA's prior conclusions that increased penalties for pharmaceutical counterfeiting are necessary, due to the significant increase of counterfeit products worldwide, and the resulting public health and safety risks such products present. Aside from counterfeiting cases, there does not appear to be evidence that the existing system for sentencing FDC Act offenses is deficient or in need of revision. Accordingly, it does not appear that wholesale changes to 2N2.1 in this area are necessary or appropriate. Moreover, before the Commission takes further action to revise this Guideline, we urge a more fully developed factual and legal record than that which has been presented to date that supports the basis for the proposed changes. Thus, apart from PhRMA's proposal to amend the Guidelines with respect to pharmaceutical counterfeiting offenses, for which we think the public record is adequate for the Commission to move forward, if the Commission is inclined to make wholesale changes

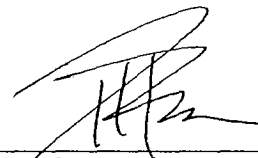
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to the existing 2N2.1 Guideline, we suggest that it first refer these issues to a Food and Drug Working Group, similar to the working group the Commission convened in 1994.

PhRMA appreciates the opportunity to comment on these proposed revisions and would be happy to provide any additional information that may be helpful to the Commission as it considers these important issues.

Respectfully submitted,


Kendra A. Martello
Assistant General Counsel


Jeffrey K. Francer
Assistant General Counsel



March 27, 2008

VIA HAND DELIVERY

Honorable Ricardo H. Hinojosa, Chair
United States Sentencing Commission
Attention: Public Affairs
One Columbus Circle, N.E.
Suite 2-500
Washington, DC 20002

Subject: Comments to Notice of Proposed Amendments to Federal Sentencing Guidelines
Federal Register: F.R. Doc. E8-1426
F.R. Publication Date: January 28, 2008

Dear Chairman Hinojosa:

The Healthcare Distribution Management Association (HDMA) appreciates this opportunity to provide public comments on the notice of proposed amendments to federal sentencing guidelines, policy statements and commentary, as published in the Federal Register on January 28, 2008.¹ HDMA and its members are the vital link in a healthcare system that assures medicine safety, quality, integrity and availability in the marketplace. A detailed description of the role of HDMA in the pharmaceutical supply chain is enclosed as an addendum to these comments.

The following comments are submitted in response to a proposed amendment to the federal sentencing guidelines which would change how certain violations of the Federal Food Drug and Cosmetic Act, ("FFDCA") 21 U.S.C. Section 301 et seq., and the Prescription Drug Marketing Act of 1987 ("PDMA"), are treated under Section 2N2.1 of the sentencing guidelines. Section 2N2.1 of the federal sentencing guidelines applies to violations of statutes and regulations involving any food, drug, biological product, device, cosmetic or agricultural product. HDMA's comments shall be limited to this proposed amendment, which is of primary importance to wholesalers of drugs, biological products, devices, and cosmetics.

Proposed Amendment Comments

HDMA shall address two issues for comment regarding Section 2N2.1 of the proposed guidelines:

- I. The need for increased or alternative base offense levels for certain offenses under Guideline Section 2N2.1
- II. The proposed amendments should not negatively affect the role of wholesale pharmaceutical distributors in conducting legitimate commercial drug transactions under Guideline Sections 2N2.1 and 2D1.1

¹ 73 Fed. Reg. 4931 (January 28, 2008).

¹ The need for alternative base offense levels under the proposed amendment

The Commission has requested comment on whether Section 2N2.1 violations should be amended in order to adequately address numerous statutes referenced in that guideline. Specifically, the Commission invites comment on whether it should provide alternative base offense levels for violations of statutes under the FFDCA and PDMA that would warrant increased sentences as listed in the sentencing guidelines. Individuals and entities found to have violated the statutes referenced in the sentencing guidelines are subject to both civil and criminal penalties, ranging from fines and monetary penalties of \$1,000 to \$1,000,000 and imprisonment from one year to ten years for serious violations of the statutes.

HDMA supports the overall goals of the Commission to strengthen and enhance the sentencing guidelines that are used by the courts against individuals for violations of the FFDCA and PDMA. Violations of these statutes threaten the safety, security and integrity of the pharmaceutical distribution industry and the supply chain system. HDMA endorses the Commission's efforts to re-examine the need for enhancing the base offense levels designated in the federal sentencing guidelines in order to assess the propriety and reasonableness of such penalties imposed against individuals who violate these statutes.

Because the proposed amendment to 2N2.1 could have a substantial impact on sentences imposed under such a wide range of regulatory offenses, adoption of the measure could lead to unforeseen consequences. Adopting the proposed amendments to the guideline would affect a substantial number of statutes referenced in the commentary to Section 2N2.1 of the guideline, including those statutes listed in Appendix A to the guidelines. Statutes affected under the proposed amendment range from misdemeanors to felonies with knowledge and intent requirements. Title 21 U.S.C.A. Section 331 and Section 333, contain descriptions of numerous prohibited acts and penalties, such as counterfeiting, illegal drug purchases and sales, and prescription drug marketing violations that could be directly affected by the proposed amendment.

At present, there is no indication that changes to Section 2N2.1 with respect to Food, Drug, and Cosmetic (FDC) Act offenses are necessary or appropriate.² In view of the structure of the FDC Act and the actual enforcement of the Act, it would appear that the Food and Drug Administration does not suffer any impediment to vigorous enforcement and maintenance of important deterrence incentives over regulated industries.

² These comments are limited to offenses to which the Section 2N2.1 guideline is applicable, and not to any offense implicating "intent to defraud or mislead" under the FDC Act, in which case the Section 2B1.1 guideline applies. Specifically, HDMA has an extensive public record regarding its concerns about the serious issue of counterfeit drugs entering the U.S. supply system. Such criminal conduct, however, would involve fraud, and therefore be governed by the Section 2B1.1 Guideline. HDMA will continue its efforts with FDA and other federal and state authorities to develop and implement the most effective and efficient methods for tracking, tracing, and authenticating pharmaceutical products' movement across the supply chain. HDMA urges federal authorities to vigorously investigate and prosecute prescription drug counterfeiting cases, and to seek the strongest possible sentences against those who would defraud vulnerable patients when they are seeking therapy and healing. HDMA further urges the Congress to conduct appropriate oversight over the Department of Justice and FDA to ensure that departmental and agency resources are appropriately deployed to address the significant public safety risks engendered by counterfeit prescription drugs.

HDMA recommends that the Commission study this matter further before it takes any final action to ratify the adoption of this amendment. HDMA believes that the Commission should have an opportunity to examine and evaluate all of the empirical data available that addresses the need to amend Section 2N2.1. Specifically, the Commission should review the historic record of prosecutions under the misdemeanor provisions of the FDC Act only and those prosecutions under of the felony provisions of the Act. We respectfully submit that such a historical review will disclose that those cases that presented substantial risks to the public health have consistently been prosecuted under the "intent to defraud or mislead" felony provisions of the Act, making the Section 2N2.1 guideline inapplicable. Enhancement of the Section 2N2.1 guideline to include the basis for an upward departure in the event of substantial risk of bodily harm or death is therefore unwarranted. Misdemeanor FDC Act prosecutions are effectively strict liability cases. *United States v. Park*, 421 U.S. 658 (1975). Enhancing that strict liability based upon the nature of the product (especially where the nature of and inherent risks of pharmaceutical products distributed can vary so widely) does not serve the underlying deterrent value of the FDC Act's misdemeanor provisions but only adds unquantifiable risk to legitimate distribution of these products.

We believe that a review of all available data supporting the addition of alternative base offense levels under Section 2N2.1 would help to ensure that the issues intended to be remedied by the adoption of guideline Section 2N2.1 are adequately addressed. Additional consideration by the Commission could avoid or reduce the chances of encountering unforeseen consequences when Section 2N2.1 guidelines are applied to violations of the referenced statutes.

II The role of distributors in conducting legitimate commercial drug transactions

Distributors provide a broad range of essential services to their customers, and maintain the reliability, safety and efficiency of the pharmaceutical supply chain. Distributors consolidate regional shipments of medications, maintain product safety inventory stocks, and disseminate products when and where they are needed. These and many more services are provided by distributors to meet the needs of their customers and to ensure that needed medicines and other pharmaceutical products will be available to them safely, efficiently, and on time.

Because of the vital role of wholesale distributors in the pharmaceutical supply chain, HDMA urges the Commission to consider the following recommendations concerning prohibited acts and penalties contained in 21 U.S.C. A. Section 331 and Section 333 as they relate to the proposed amendment to Sections 2N2.1 and 2D1.1:

1. We urge the Commission to recognize the unique role of pharmaceutical distributors when it considers alternative base offense levels for prohibited acts under the sentencing guidelines. Specifically, we ask that the Commission consider the unique role of pharmaceutical distributors as it deliberates amending the sentencing guidelines for violations of counterfeiting, or the doing of any act which causes a drug to be a counterfeit drug, under 21 U.S.C.A. Section 331. We believe that the Commission should refrain from adopting any alternative amendment to the sentencing guidelines that would incorporate base offense levels for the unknowing and unintentional distribution of counterfeit drugs through the supply chain by wholesale distributors. In those cases in which the

government has found it necessary to seek lengthy sentences, there have been circumstances which fully enable prosecutors to use a panoply of criminal statutes to achieve appropriate charging decisions. E.g., *United States v. TAP Pharmaceutical Products, Inc.*, 1:01-cr-10354-WGY (D. Mass.) (judgment Dec. 10, 2001) (conspiracy, conspiracy to defraud, anti-kickback, and False Claims Act counts charged).

Under 21 U.S.C.A. 353, a wholesale distributor is an entity that has been granted a license by the State, and is thereby authorized to engage in commercial transactions involving the purchase and sale of prescription medications. These transactions include the purchase and sale of controlled substances not safe for use unless under the supervision of a physician. The language contained in Section 331 and Section 353 referenced above recognize the authority of distributors to conduct transactions involving these substances, and therefore prohibitions in the statute against the sale, or purchase of drugs applicable to individuals or unlicensed entities, do not apply to them. We ask that amendments to Section 2N2.1 or related guidelines reflect the language contained in these statutes.

2. The Commission also requested comment regarding the harmfulness of human growth hormone (hGH) offenses relative to offenses involving anabolic steroids. Specifically, the Commission invites comment on whether the trafficking of hGH is more harmful, less harmful, or of equal harm to the trafficking of steroids. The proposed amendment would potentially expand the scope of base level offenses under Section 2D1.1(b)(6) of the sentencing guidelines, and would equate hGH to a controlled substances for purposes of their treatment under the sentencing guidelines.

In its consideration of base offense levels for hGH violations, HDMA urges the Commission to maintain the distinction between the use of the term distribution as a legitimate commercial service provided by wholesale distributors in the normal course of business, from the term as it is used in the context of the prohibited acts and penalties under 21 U.S.C.A. section 331. In the former context, the term distribute means to sell, offer to sell, deliver or offer to deliver a drug to a recipient as part of a wholesale distribution transaction. Wholesale distribution is defined under the PDMA as the distribution of prescription drugs to persons other than a consumer or patient. HDMA's concern is that the use of the term in the context unrelated to wholesale distribution transactions may be used inappropriately when considering the application of the proposed amendment to Section 2D1.1 of the guideline, and could result in avoidable confusion over its use and interpretation.

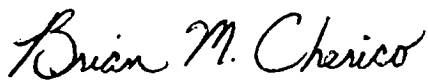
Conclusion

In summary, HDMA believes that the Commission should recognize the importance of the current role of the wholesale pharmaceutical distributors as it considers the consequences of adopting amendments to the proposed sentencing guidelines. We urge the Commission to refrain from adopting any amendment that would result in directly or indirectly having a negative affect on the necessary commercial activities and administrative services performed by wholesale distributors in the normal course of business.

* * * * *

On behalf of HDMA and our member companies, thank you for the opportunity to provide our comments on the Commission's proposed amendment to Section 2N2.1 violations under the federal sentencing guidelines. We are grateful for the opportunity to relay our perspective about important supply chain issues, and we continue to stand ready to address any questions you may have about the issues, concerns, and suggestions discussed above.

Sincerely,

A handwritten signature in cursive script that reads "Brian M. Cherico".

Brian M. Cherico, Esq.
Government Affairs

ADDENDUM

HDMA – The Vital Link in the Safe Delivery of Medicines in the U.S.

The Healthcare Distribution Management Association (HDMA) is the national association representing primary, full-service healthcare distributors. Each day, the member companies of HDMA are responsible for ensuring that more than 13 million prescription medicines and healthcare products are safely delivered to 144,000 pharmacies, hospitals, nursing homes, physician offices, clinics, government and other providers in all 50 states. This essential public health function is provided with tremendous efficiency, saving the nation's healthcare system nearly \$34 billion each year. HDMA and its members are the vital link in the healthcare system, working daily to provide value, remove costs and develop innovative solutions to deliver care safely and effectively.

Healthcare Distribution At-A-Glance

- Through value added-services, including streamlined logistics and efficient operations, distributors save the healthcare system nearly \$34 billion each year
- 80% of prescription medicines sold in the United States are stored, managed and delivered by HDMA member companies
- Healthcare distributors represent 3% of the total cost of prescription medicines
- At only 1.1 % the distribution industry net profit margin is very low

Distributors Save the Healthcare Billions of Dollars Each Year

A landmark study by the research firm Booz Allen Hamilton, commissioned by HDMA's knowledge partner, the Center for Healthcare Supply Chain Research, reported that healthcare distributors save the healthcare system nearly \$34 billion a year by providing value-added services and creating business efficiencies.

HDMA members manage many of the most sophisticated and efficient distribution facilities in the world. These distribution centers critical to the efficient delivery of prescription medicines and healthcare products from more than 1,100 different manufacturers to pharmacy settings across the country.

Distributors Are Highly Regulated By State And Federal Governments

The U.S. healthcare supply chain is one of the most sophisticated in the world, providing a strong system for the safe and efficient delivery of prescription medicines to patients nationwide. Manufacturers, distributors and pharmacies work daily to help ensure patients receive the right medicine, at the right place, at the right time. These companies together must remain vigilant in monitoring, protecting and enhancing this secure system against increasingly sophisticated criminals who may try to introduce counterfeit or diverted drugs into the legitimate supply chain.

Healthcare distributors are regulated at both federal and state levels to help ensure the integrity and security of the supply chain. At the federal level, distribution centers are subject to inspection by: The U.S. Food & Drug Administration (FDA), Drug Enforcement Administration (DEA), Environmental Protection Agency (EPA), Occupational Safety & Health Administration (OSHA) and Department of Transportation (DOT).

Furthermore, states are responsible for licensing distributors, and many states apply regulatory standards in addition to those required under federal law. These state standards apply to companies conducting business in the state, even if the company's distribution center is located in another state. HDMA continues to strongly advocate for tougher state licensing requirements for healthcare distributors to further enhance supply chain integrity and patient safety.

The Nation's Healthcare Distributors Deliver Healthcare Products And Services Every Day

HDMA member companies are the vital link in the healthcare system, providing the highest-quality business solutions that remove costs and empower providers to deliver care more effectively. The development of products requiring advanced and/or special handling, as well as the increased demand for specialized treatments among home users, would be difficult, if not impossible, to manage without the expertise of the nation's healthcare distributors.

March 28, 2008

Hand Delivered

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Attention: Public Affairs

Re: Comments to Federal Register Notice, Vol. 73, No. 18, published Monday, January 28, 2008, at pages 4931-4939; Notice of Proposed Amendments to Sentencing Guidelines.

Pursuant to section 994(a), (o), and (p) of title 28, United States Code, the United States Sentencing Commission is considering promulgating certain amendments to the sentencing guidelines, policy statements, and commentary. This notice sets forth the proposed amendments, a synopsis of each amendment, and various issues for comment. Written public comment regarding the proposed amendments and issues for comment set forth in this notice, including public comment regarding retroactive application of any of the proposed amendments, should be received by the Commission not later than March 28, 2008. (73 FR 4931-4939)

To Whom it May Concern:

On behalf of our client Air Liquide USA LLC (Air Liquide), we submit the following comments. Air Liquide appreciates the opportunity to comment on the aforementioned proposed amendments to the Sentencing Guidelines.

Air Liquide is a leading manufacturer and supplier of medical, industrial and specialty gases with manufacturing facilities in over 70 countries and U.S. corporate headquarters in Houston, Texas.

As a manufacturer and supplier of medical gases that are regulated by the U.S. Food and Drug Administration (FDA), the company has an interest in the proposed amendments to the sentencing guidelines and submits the following comments for consideration:

First, Air Liquide supports the comments as submitted by attorneys John R. Fleder and John A. Gilbert of Hyman, Phelps & McNamara, P.C., who participated in the panel testifying before the Commission regarding the proposed Guideline changes concerning

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the Federal Food, Drug, and Cosmetic Act (FDC Act) and the Prescription Drug Marketing Act (PDMA) violations. Both attorneys testified on February 13, 2008 with respect to § 2N2.1 of the proposed amended guidelines, titled "Violations of Statutes and Regulations Dealing With Any Food, Drug, Biological Product, Device, Cosmetic, or Agricultural Product." According to the Commission's proposal issued in the Federal Register:

Both Mr. Fleder and Mr. Gilbert took the position in their testimony that § 2N2.1 appears to be working as intended and that there is insufficient evidence that the § 2N2.1 Guideline needs to be revised at this time.

Second, Air Liquide is concerned that if the proposed amended Guidelines are adopted, the change would almost certainly dramatically increase sentences to be imposed in cases where "loss" is at issue (probably in all felony cases). Under the present standard of "current good manufacturing practices", the extent of compliance is meant to evolve over time. Consequently, products that are manufactured in compliance with "current" GMPs today can be out of compliance at a future date. Moreover, the non-compliant products (which were in compliance in the past) would not need to be reprocessed, retested or otherwise revised in order to be used safely and effectively, thereby meeting the health care community's or the consumers' expectations on both a therapeutic and economic level. Yet, the proposed amendments' change in how the term "loss" is defined would appear to cause all products that are out of compliance with cGMPs to be deemed valueless. Such a radical change in defining "loss" raises serious legal and policy issues that the Commission should investigate before adopting.

Additionally, the term "current good manufacturing practice" is not defined by the FDC Act itself. Instead, the law allows FDA to publish regulations to define its requirements and expectations in this area. FDA's regulations describe the minimum requirements for conforming to cGMPs in general rather than specific terms. FDA issues Guidance documents to provide specifics, but the Guidances are not legally binding.¹ Furthermore, FDA's cGMP requirements evolve over time as noted above. For example, FDA's first Guidance on compressed medical gases was issued in June 1981 and revised in 1983. In February 1989, FDA issued another revision of the Guidance, which was updated again in "draft" form in May 2003. See Guidance for Industry, Current Good Manufacturing

¹ FDA Guidance documents contain the following or a similarly-worded caveat: "This draft guidance, when finalized, will represent the Food and Drug Administration's current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. You can use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations."

United States Sentencing Commission

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Page 3

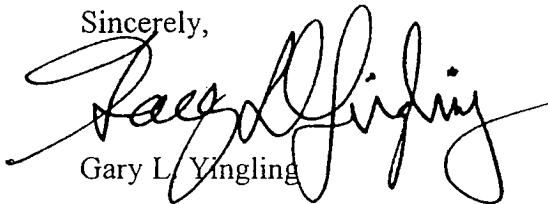
Practice for Medical Gases (Draft, May 2003), at p. 1. Because they are meant to cover a wide range of product types, the regulations use subjective terms such as adequate, appropriate, sufficient, etc., the meaning or application of which often results in disputes, which FDA recognizes.² In our view, the proposed amendments could lead to the imposition of increased sentences even in cases where the cGMP compliance violation represents a relatively "new" interpretation by an FDA investigator.

Third, Air Liquide believes FDA's position in support of the amendments is unrealistic in its scope and could lead to extended sentencing terms for minor infractions. For instance, an FDA-regulated product is deemed misbranded if the product was manufactured at a registered facility, but the particular product was not properly listed. Similarly, many FDA-regulated products are deemed adulterated if they have been manufactured outside the very general cGMP requirements, even if the cGMP deficiency cited by a particular FDA investigator involved an issue such as a record-keeping mistake that does not affect the inherent identity, strength, quality or purity of the product.

Given the multi-national, multi-faceted and multi-sited traits of many FDA-regulated companies that will be governed by the Sentencing Guidelines, it is imperative that the Commission ensure that any amendment to the specific language, general policies or commentary of the Sentencing Guidelines preserve the present balance between real-world common sense and strict liability for corporate officers.

In conclusion, Air Liquide would like to thank the Commission for its consideration of these comments and would like to reinforce that current guidelines are sufficient and believe the amendments should be disallowed.

Sincerely,



Gary L. Yingling

² "Disputes related to scientific and technical issues may arise during FDA inspections of pharmaceutical manufacturers to determine compliance with cGMP requirements or during the Agency's assessment of corrective actions undertaken as a result of such inspections. As these disputes may involve complex judgments and issues that are scientifically or technologically important, it is critical to have procedures in place that will encourage open, prompt discussion of disputes and lead to their resolution." Guidance for Industry, Formal Dispute Resolution: Scientific and Technical Issues Related to Pharmaceutical CGMP (January 2006), at p. 1.



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March 6, 2008

Thomas D. Brown
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Dear Mr. Brown,

Please find enclosed my observations regarding human growth hormone distribution and suggestions regarding sentencing guidelines for growth hormone distribution related offenses.

Thank you very much for your and the Commission's willingness to consider my comments.

Most Sincerely,

Thomas Perls MD, MPH
Associate Professor of Medicine
Boston University School of Medicine

BOSTON UNIVERSITY MEDICAL CENTER

Boston Medical Center
Boston University School of Medicine
Boston University School of Public Health
Boston University Henry M. Goldman School of Dental Medicine

[101]

Thomas Perls, MD, MPH
Associate Professor of Medicine
Boston University School of Medicine

Sentencing of human growth hormone offenses
Submitted to the United States Sentencing Commission

March 6, 2008

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Introduction

My name is Thomas Perls MD, MPH. I am board certified in Internal Medicine with added qualifications in Geriatrics and I am a Fellow of the American College of Physicians. I am an Associate Professor of Medicine at the Boston University School of Medicine and I am clinical staff at Boston Medical Center. I also direct the New England Centenarian Study (www.bumc.bu.edu/centenarian) and I receive funding from the National Institute on Aging for my research activities. Over the past 10 or so years I have become increasingly aware of the marked growth in the anti-aging industry and its promotion of scientifically unfounded claims while anti-aging clinics and websites sell drugs such as testosterone and growth hormone to gullible clients. In 2005, I was lead author of a paper published in the Journal of the American Medical Association (JAMA), titled "Growth hormone for "anti-aging": Clinical and Legal issues".¹

With my continued monitoring of the industry and the germane scientific and clinical literature, I was recently asked to be a medical expert witness, appearing before the U.S. House of Representatives' Oversight Committee the day before the Roger Clemens – Brian McNamee hearing, in order to answer the committee members' questions about growth hormone. My expertise and clinical background has also led to the Drug Enforcement Agency (Arizona and New York offices) and Assistant U.S. Attorney (Denver) to seek my expertise in assisting with the evaluation of clinical practices by medical practitioners and compounding pharmacies distributing growth hormone and testosterone for anti-aging (alternatively called hormone-replacement programs, age-management or longevity medicine).

I feel it is extremely important to point out to the Commission the brazen and what I see as wide-spread and highly marketed and promoted illegal and medically dangerous distribution of growth hormone particularly by members of the anti-aging industry.

In the course of my reviewing DEA-seized medical records from several anti-aging clinics, I was aghast at what I observed as repeated and obvious ethical and professional misconduct as well as the breaking of numerous State and Federal laws. It is in part, out of my concern for the past, present and future

patients of these and many other clinics, that I am writing this summary of observations and suggestions to you.

Growth Hormone Deficiency in Adults

HGH levels gradually decline in adults with minimal or no negative health consequences for the vast majority of the population. The anti-aging industry, the primary pusher and seller of hGH in this country, advertizes that normal declines in hGH cause decreases in strength, muscle mass, sleep, and sexual performance. They go on to claim that replenishing growth hormone to levels present at younger ages stops or reverses these problems as well as aging itself.^{2, 3} This is a ruse.⁴⁻⁷

There are a few medical conditions in adults that merit the use of growth hormone.

The Medically Appropriate and Legal Indications for hGH Distribution

Recognizing the potential for growth hormone abuse, Congress amended the Food Drug and Cosmetic Act in the late 1980s and early 1990's⁸ stipulating that hGH can be distributed to adults for only three specific indications approved by the Secretary of Health and Human Services.^{9, 10}

1. AIDS Wasting Syndrome
2. Short bowel syndrome, and
3. Growth Hormone Deficiency (GHD)

GHD is very rare, occurring at a rate of about 1 adult out of 10,000¹¹ and the legal diagnosis requires documentation of disease, such as a cancer, or trauma to the pituitary gland and a failed stimulation test.¹² Often times, GHD is accompanied by deficiencies of other pituitary gland-produced hormones.

In January, 2007, the FDA released an alert reminding those that distribute growth hormone for anti-aging, body-building and athletic enhancement that they are doing so illegally.¹³

In response to government statements that hGH distribution for anti-aging is illegal, compounding pharmacies and anti-aging clinics that distribute hGH have received advice from Rick Collins JD and others to now claim that they are distributing or prescribing the drug for an FDA-approved indication, presumably adult growth hormone deficiency (GHD).^{14, 15} According to the FDA and the American Association of Clinical Endocrinologists (AACE), a legal and legitimate diagnosis of GHD **must** include (1) an evaluation of the anterior pituitary gland demonstrating an inadequate response to a stimulation test

(hGH level $<5 \mu\text{g/L}$), and (2) demonstrated clinical or pathological evidence of pituitary disease or trauma or documented GH deficiency in childhood.¹⁶

The package inserts for four of the five brands of hGH approved for GHD: Genotropin (Pfizer),¹⁷ Humatrope (Eli Lilly),¹⁸ Norditropin (Novo Nordisk),¹⁹ and Nutropin (Genentech)²⁰ all mandate diagnostic criteria consistent with the FDA and AACE positions. For reasons unknown, the package insert for Saizen (Serono)²¹ uses the word "should" instead of "must" with regard to the need for a stimulation test; an ambiguity that some in the anti-aging industry use as a loophole to avoid the stimulation test.¹⁵ Serono should correct its package insert. Even if the stimulation test is not performed, legal distribution of hGH still requires the demonstration of clinical or pathological evidence of disease, and the FDA has been clear that aging is not a disease. Making the diagnosis of GHD on the basis of IGF-1 levels without the documentation of hypothalamic or pituitary disease is inaccurate²² and I contend that it is both medically unethical and unprofessional to prescribe or administer hGH to the greater than 99 percent of the public²³ who do not meet the FDA's and AACE's diagnostic criteria for GHD.

Use of hGH Supplementation in Healthy Adults and Potential Risks

A recent Stanford University review of 31 clinical studies of hGH use among healthy, normally aging individuals found the only benefit to be a slight increase in muscle mass. The documented negative side effects included soft tissue swelling, joint pains, carpal tunnel-like syndrome, breast enlargement, and diabetes.²⁴ Other side effects include liver and heart enlargement, increased pressure around the brain (called pseudotumor cerebri) and high blood pressure. In a 2002 Johns Hopkins study published in JAMA, about 50% of subjects experienced side effects, primarily joint pains and extremity swelling. 13% developed elevated blood sugars or diabetes.²⁵

Ironically, there is no credible scientific evidence that hGH substantively increases muscle strength or aerobic exercise capacity in normal individuals.²⁵⁻²⁸ Recent experiments in laboratory mice by Bonkowski et al.,²⁹ Coschigano et al.,³⁰ and a recent study in centenarians³¹ reaffirm the observation that GH deficiency or resistance to GH action is associated with *longer* life spans, not *shorter* ones.

With regard to the most feared risk of hGH administration, cancer, Smith and colleagues cite 3 studies demonstrating strong associations between endogenous levels of insulin-like growth factor-1 (IGF-1) and prostate, colon and pre-menopausal breast cancer, and they posit potential mechanisms for how IGF-1 and hGH promote cancer.³² Sonntag et al. document evidence that hGH and artificially elevated IGF-1 levels are risk factors for lung, breast, and prostate cancers.³³ Conway-Campbell and colleagues

demonstrated that growth hormone induces tumor formation and progression in rats, and enhances metastases or spread of cancer.³⁴

In the context of these and other studies, and in the absence of long-term human studies proving the safety and efficacy of hGH in normally aging adults, the claim that "the side effect profile of (h)GH therapy is nominal..."³⁵ is not supported by empirical evidence. It is theoretically possible that declines in hGH experienced as a function of age is an adaptive response to accumulating cell damage^{36, 37} and offers protection from various age-related diseases (e.g. cancer).

Illegal and Medically Inappropriate Distribution of hGH

Since 1990, a growing network of compounding pharmacies, anti-aging clinics, and physicians have created what some within the industry estimate is a 2 billion dollar-a-year business for distributing hGH³⁸— a distribution network involving hundreds of thousands³⁹ of weight training enthusiasts, practitioners and promoters of anti-aging medicine, and those who have fallen victim to growth hormone replacement scams.

I personally have found websites of 279 anti-aging clinics that advertise hGH treatment and 26 pharmacies that distribute the drug to these clinics or sometimes directly to users. I have certainly discovered only a fraction of what exists out there (see figure 1, below).

Sample of
Compounding pharmacies n=26 &
Anti-aging, age-management, longevity, rejuvenation or wellness clinics n=276
advertising on the internet that they provide growth hormone

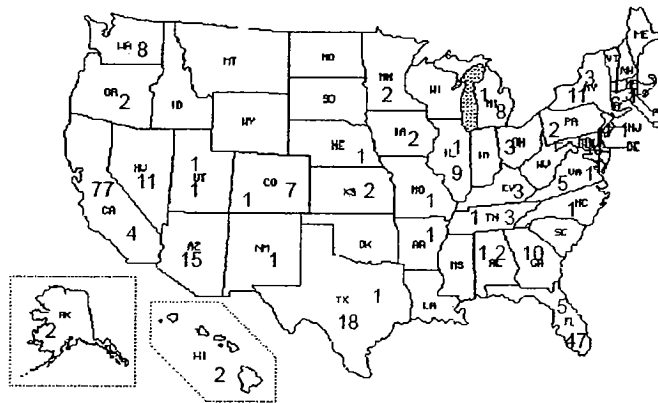


Figure 1

Researched and constructed by Thomas Perls MD, MPH for the Oversight Committee, House of Representatives. February, 2008

Of the seized anti-aging clinic records I have reviewed for the DEA, the average patient that first presents to the clinic is not a person in their 60s or 70s seeking alleviation of their age-related problems, but rather, a male in his late 20's to mid 40's, weight training nearly daily, in otherwise excellent health, clearly seeking anabolic steroids and hGH.

A Case Example of an Anti-Aging Clinic's Promotion and Sale of Human Growth Hormone:

The below is my summary of a doctor who owns and runs an anti-aging clinic, whose medical records and website I reviewed for the DEA.

Dr. M, is an Arizona based physician who runs the M anti-aging clinic, which is advertized on the internet and in brochures as an anti-aging clinic. He indicates that he is board certified in anti-aging medicine. All of the patients under Dr. M's care that were reviewed by me were placed on a "hormone replacement program" that included not only growth hormone but also hormones such as testosterone, pregnenolone, dihydroepiandrosterone (DHEA), human chorionic gonadotropin (HCG), thyroid hormone and drugs that increase testosterone levels such as arimidex. These hormone replacement programs are

invariably very expensive (about \$15,000 per year) and most patients were also sold expensive vitamin supplements (about \$1,200 per year). The average age of the 19 patients reviewed was 43 yrs old, with a range from 30 yrs to 60 yrs. Nearly all were in very good physical condition upon presentation except for a man with chronic fatigue syndrome and a few patients with medical problems that in my opinion were either ignored by or went unrecognized by Dr. M.

The hormone replacement programs that the patients were placed on are similar to anabolic steroid and growth hormone regimens used by body builders. In fact, many of Dr. M's patients that were reviewed were body builders and some were already on anabolic steroids, growth hormone and other drugs before coming to his clinic. As such, most of the patients reviewed appear to be coming for body building drug regimens and were clearly seeking more anabolic steroids, growth hormone and other drugs.

Whether one calls the therapies these patients were receiving body-building or anti-aging, in either case, the hormones and care provided by Dr. M fell far outside what would be regarded as standard medical care, even by alternative or complementary medicine standards. In my opinion, the health related risks that Dr. M exposed these patients to far outweighed any benefit. There were numerous instances of side effects or illnesses in which these drugs would worsen the patient's condition(s) including various serious ones such as cardiac arrhythmias, elevated blood sugars (pre-diabetes), and obstructive sleep apnea.

Despite most of the patients generally being in good physical condition with normal laboratory values, Dr. M provides a statement that in several variations appears in nearly all the charts of his that I reviewed: "After about a 2.5 hr discussion on anti-aging medicine, all aspects of the treatment plan, each of the hormones and particularly all the risks and benefits of them the following program was formulated." And he goes on to assert the following problems, which in nearly all the cases, again cannot be supported by the data.

- Low level deficiency of Growth Hormone
- Low level deficiency of Testosterone
- Low level deficiency Thyroid
- Low level deficiency DHEA

Even if Dr. M claims after the fact that some of the levels fall at the low end of normal limits, even in the remotest extreme of standard medical practice, provision of hormones to most of the patients I reviewed was not only unwarranted, but because of potential side effects, they were contra-indicated.

In all the cases I reviewed, Dr. M sold human growth hormone (hGH) directly to the patients, and there was not in any instance medical history or laboratory evidence supporting a diagnosis of Adult Growth Hormone Deficiency Syndrome (AGHDS) alternatively called Growth Hormone Deficiency (GHD) which would be required in order to legally prescribe, distribute/sell and administer HGH to these patients. The IGF-1 levels were almost always within normal range, but it must be noted that even IGF-1 levels are lower than normal, this would not be enough to make an accurate diagnosis of AGHDS (an extremely rare diagnosis, occurring in about 1 per 10,000 adults).⁴⁰ As detailed below, patients accurately diagnosed with this syndrome or disorder would need clinicopathological evidence of damage to their anterior pituitary gland and would have to fail a growth hormone stimulation test.

Consensus statements by the American Association of Clinical Endocrinologists (AACE)¹⁶ and the GH Research Society in association with the European Society for Pediatric Endocrinology, Lawson Wilkins Society, European Society of Endocrinology, Japan Endocrine Society, and Endocrine Society of Australia⁴¹ have been published indicating that hGH should not be used for anti-aging.

The patients were usually also provided with other hormones including testosterone, thyroid hormone and DHEA, also unwarranted, again in nearly all the cases, given the normal lab values and lack of clinical symptoms. One might argue that thyroid supplementation is warranted by anticipating a potential hypothyroidism caused by anabolic steroid administration, but firstly the patients should not be on steroids in the first place and second one should prove the diagnosis of hypothyroidism before providing thyroid supplementation.

All the billing I observed was on a cash-only business with patients providing credit card numbers that would be billed for the provision of drugs and services. Typically, growth hormone alone cost about \$3,000 to \$4,000 every 3 months.

There was also typically a \$600 professional fee, again about every 3 months. Of course there were also charges for all the other drugs eg. Testosterone, arimidex, HCG, pregnenolone, DHEA and thyroid hormone. Importantly, these drugs were directly distributed to the patient along with syringes, on the M anti-aging clinic premises. In a few cases, growth hormone was sent, interstate (therefore violating the law concerning interstate distribution of GH) from Arizona to California and Wisconsin. As you can see, patients were spending huge amounts of money from \$3,000 to \$4000 every 3 months.

Below, I indicate specific instances of what I believe to be violations of medical ethical and professional conduct, Arizona law statutes and Federal law, as well as Federal Trade Commission laws, by Dr. M.

Ethical Misconduct:

1. Conflict of Interest. Dr. M, sold growth hormone at a considerable profit to his patients without letting them know he was making money on the drug he was telling them they needed. This constitutes professional misconduct.⁴²

According to the document, "The Arizona Medical Board's Guidelines For Physicians Who Incorporate Or Use Complementary Or Alternative Medicine In Their Practice", such a sale of drugs at a profit constitutes a conflict of interest (e.g. the doctor's decision to sell hGH to the patient could be swayed by the profit he makes on the drug).⁴³ Particularly in the setting of not disclosing his financial interest in the sale of these products to the patient, this is ethical misconduct.

2. Misleading or False Claims in Advertising.

- a. In a M Anti-aging clinic advertisement brochure, the following claims appear: *"In combination with proper diet, exercise and nutritional supplements, total hormone restoration therapy has consistently shown to slow down and even reverse the aging process"*.⁴⁴ There has been no credible evidence in the scientific literature supporting these claims.
- b. The brochure and the November, 2006 version of the M Anti-aging clinic website also state the following: *"Improving the quality of life with an appropriate anti-aging program has shown these proven benefits: Reduce fat, increase lean muscle mass, increase energy level, improve exercise endurance, improve long and short term memory, improve sexual performance and libido, boost the immune system, reduce risk of osteoporosis, reduce risk of cardiovascular disease, minimize symptoms of menopause for women and andropause for men, thickens and reduce wrinkles."* These panacea-like claims are common in the antiaging industry and are misleading at best. No therapy has been demonstrated to do all of these things, particularly one specific to an "anti-aging program". A conscientious and effective program of exercise, diet and not smoking will do many of these things. There is no evidence that the addition of the hormones and supplements prescribed and in most cases distributed and sold by Dr. M will provide any additional benefit in achieving these goals. If anything, over the long term this regimen could cause substantial physical harm.

- c. On the November, 2006 version of the M Anti-aging clinic website, the following statement appears: *"Myth: Anti-aging medicine is a non-mainstream, alternative field of medicine. Fact: Anti-aging medicine is a widely accepted field of medicine. Just like internal medicine or orthopedic surgery, there is a Board..."* By indicating that there is a "Board" of anti-aging medicine, Dr. M attempts to provide a false sense of credibility. There is no American Board of Medical Specialty (ABMS)-recognized Board of anti-aging medicine. Elsewhere on the website, Dr. M states that he is an active member and diplomat of such a board and organization. In addition to the fact that providing a false credential is unethical, this might also violate Arizona law; that is, claiming board certification in a medical specialty that would not be recognized by the Arizona Medical Board.^{45, 46}

Some telling quotes from Dr. M with my comments in brackets...

- (a) M: "However, the past 10-plus years of study show that anti-aging programs have been associated with less disease, lower morbidity and better quality of life."⁴⁷

[I know of no such studies that have passed unbiased peer review]

- (b) M: "Everything I do, including the way I administer hormones and supplements, is based on hundreds of studies that support anti-aging medicine and its safety and efficacy."⁴⁷

[Again, I am unaware of unbiased peer reviewed clinical studies that support this statement which is commonly stated by members of the Anti-Aging industry]

- (c) "Years of scientific research have shown a major part of the aging process is the decline of many crucial hormone levels from their youthful peaks. In combination with proper diet, exercise and nutritional supplements, total hormone restoration therapy has consistently shown to slow down and even reverse the aging process"⁴⁴

[This is an unfounded statement. There are no unbiased peer reviewed studies demonstrating that hormone replacement therapy slows or reverses aging.]

Such misleading and/or scientifically unsubstantiated advertising is ethical misconduct. According to The Arizona Medical Board's "Guidelines For Physicians Who Incorporate Or Use Complementary Or Alternative Medicine In Their Practice": *"In advertising a practice or while*

*consulting with a patient, a physician may not make false or fraudulent claims. A physician may not claim that a particular treatment can cure, alleviate or ameliorate a disease or condition unless the claim is supported by valid, conventional science. A physician's personal experience, patient testimony and other anecdotal evidence is not sufficient evidence to support a claim of a treatment's efficacy and safety."*⁴⁸

3. Unproven Efficacy and Unsafe Treatment Plan. In all the charts I reviewed, Dr. M states some variation of the following: "After about a 2.5 hr discussion on anti-aging medicine, along with the risks and benefits of all the hormones the following program was designed for the patient."

On the November, 2006 version of the M Anti-aging clinic website, the following is also stated: "**Total Hormone Restoration** This involves measuring and restoring to youthful levels all of your important hormones. These include human growth hormone (HGH), testosterone, DHEA, melatonin, thyroid, pregnenolone, (and estrogen and progesterone in women). Determining which, and how much of each hormone is based on medical history, physical exam, age-related testing, and blood tests. Because the cost of growth hormone is significant, programs excluding HGH are available." Given the advertising and his discussion of anti-aging medicine with the patient, it is clear that Dr. M is providing multiple hormones and neutraceuticals as a part of what he calls an "anti-aging program". Particularly, in most cases, in the face of no laboratory evidence of any hormone deficiencies "Total hormone restoration" falls completely outside the realm of an alternative medicine treatment where, according to the Arizona State Medical Board, there must be a well-founded expectation of benefit to the patient. In addition, the hormone replacement regimen provided to this patient poses more than minimal risk. Specifically, testosterone replacement may increase patients' long term risks for cardiovascular and cerebrovascular disease.^{49, 50} Anastrozole (Arimidex) and HCG, also frequently given to the patients, also increase testosterone levels and therefore also increase vascular risk. Other drugs commonly provided as part of Dr. M's "hormone replacement program", Pregnenolone and DHEA, are prohormones of testosterone and can also lead to testosterone-related side effects.

Some notable quotes from Dr. M along with my comments in brackets:

(a) "There are four parts to any anti-aging regimen, says M: proper diet, proper exercise, proper supplementation and hormone restoration therapy"⁴⁷

[Endocrinologists would argue that there are not clinical studies supporting “hormone restoration therapy” particularly in the case of HGH and normal aging.]

(b) “For instance, human growth hormone has become known as a very important factor in how fast a person ages, Growth hormone levels tend to diminish as we get older. Maintaining higher levels of growth hormone result in less body fat, more muscle, improved libido, thicker skin, less wrinkles, better immune function, and much more.”⁵¹

[Such panacea-like claims are common in the antiaging industry literature with no studies supporting such global benefits. Several studies have shown minor improvements in muscle mass (but not strength), decreased body fat and no improvement in the other claimed benefits. They don’t mention the high rates, up to 50%, of adverse side effects (organ enlargement, carpal tunnel like syndrome, glucose intolerance, and hypertension) and 13% who can develop diabetes.^{25, 52}]

[c] “Patients in their early 60s, 70s, and 80s have been experiencing dramatic results according to M. ‘Patients over 60 may feel the benefits sooner, and they may be more pronounced, but starting the program at a younger age (35-40) may provide the maximum long-term benefits,’ says M”⁴⁷

[Given the increased risk with aging for many different cancers, older patients may be the most at risk to the cancer potentiating effects of GH. There are no long term studies of GH administration.]

The use of unsafe and not previously demonstrably effective treatments is experimental in nature and a physician who wishes to use such a treatment should only do so under rigidly controlled conditions that meet all State and National standards and protocols for research including submission of the proposed treatment to an Institutional Review Board for approval.⁵³ In addition to therefore being unethical, the provision of hormones classified as drugs under these conditions meets the criteria of professional misconduct.⁵⁴

Professional Misconduct (According to Arizona State law)

1. Arizona State Legislature, 32-1401 states that “Unprofessional Conduct” includes the following: (j) Prescribing, dispensing or administering any controlled substance or prescription-only drug for other than accepted therapeutic purposes.⁵⁴ For the details of how this pertains to Dr. M, see “Unproven Efficacy and Unsafe Treatment Plan”, above.

Along the same lines, Dr. M's "total hormone replacement" or the provision of HGH in particular, especially in the setting of no proven deficiency either clinically or by laboratory standards, would also violate another rule of misconduct: (y) The use of experimental forms of diagnosis and treatment without adequate informed patient consent, and without conforming to generally accepted experimental criteria including protocols, detailed records, periodic analysis of results and periodic review by a medical peer review committee as approved by the FDA or its successor agency.⁵⁵

3. Arizona State Legislature, 32-1401. Definitions 27 "Unprofessional conduct" includes the following, (mm) The representation by a doctor of medicine or the doctor's staff, employer or representative that the doctor is boarded or board certified if this is not true or the standing is not current or without supplying the full name of the specific agency, organization or entity granting this standing.⁵⁶ Given that board certification in anti-aging medicine is not recognized by the American Board of Medical Specialties, the representation by Dr. M that he is board certified in Anti-Aging Medicine is false and misleading. Along the same lines, another statute may be violated (bb) Representing or holding oneself out to being a medical specialist when such is not the fact.⁴⁶

Of note, Dr. M was quoted in a Phoenix magazine article: "anti-aging medicine is a bona fide field of medicine just like internal medicine or pediatrics."⁴⁷

4. Arizona State Legislature, 32-1401. Definitions. 27. "Unprofessional conduct" includes the following, whether occurring in the State or elsewhere. (hh) Prescribing, dispensing or administering anabolic-androgenic steroids to a person for other than therapeutic purposes. Nearly all the patient records I reviewed did not demonstrate clinical histories, or physical or laboratory findings to support the prescribing of testosterone or Deca Durabolin (nandrolone).

Violating Arizona Criminal Law

1. Arizona Revised Statute, ARS 32-1996E states "A person who dispenses human growth hormone in violation of this chapter is guilty of a class 6 felony". The chapter being referenced by this statute subsection is chapter 18, title 32.

2. Arizona Revised Statute, 13-3401.6.(d).(xxii) designates testosterone as a "dangerous drug", and the Arizona criminal statute for illegal distribution of testosterone is ARS 13-3407A7. As noted above, testosterone therapy cannot be justified in the cases of most of the patient records I reviewed within the realm of a reasonable standard of medical care. In the cases of patients who may have obstructive

sleep apnea, or whose PSAs or bad cholesterol profiles increased over the course of treatment, the testosterone may truly be manifesting itself as dangerous.

Violating Federal Law

1. Dr. M prescribed, distributed and/ administered (see medication administration log) hGH without meeting any of the legally allowed adult indications for hGH (AIDS wasting syndrome, short bowel syndrome, and Adult Growth Hormone Deficiency Syndrome, AGHDS), alternatively named Growth Hormone Deficiency (GHD).^{1, 13} As further discussed below, according to Federal law, to appropriately and legally justify administration of hGH for AGHDS, one must perform an appropriate anterior pituitary stimulation test (e.g. with growth hormone stimulation hormone, arginine, and much more rarely, insulin) and measure a less than minimum response in GH production along with a clinicopathological finding to explain the relative anterior pituitary responsiveness.^{9, 10, 13}

As is the case for anabolic steroids, the legal provision and distribution of hGH is narrowly defined. In 1988 and again in 1990, Congress amended the Food, Drug, and Cosmetic Act (FDCA) to enact more stringent controls with higher penalties for offenses involving the distribution of anabolic steroids and hGH [codified at 21 USC §333(e)(1)].⁹ In 1993, the provisions outlawing the distribution of specifically growth hormone were recodified as 21 USC §333(f) (pursuant to PL No. 103-80, §3(e), 107 Stat 775). Section 303 (f)(1) of the FDCA permits distribution of hGH in connection with (1) "treatment of a disease" or (2) "other recognized medical condition" that has been authorized by the Secretary of Health and Human Services.^{9, 10}

Please note the potential confusion in the code: As noted above, the provisions outlying the distribution of specifically growth hormone were recodified as 21 USC §333(f) (pursuant to PL No. 103-80, §3(e), 107 Stat 775). Yet, the code is frequently cited as 21 USC §333(e) - even in the current proposed amendments to the sentencing guidelines.

Provision of hGH is legal for children with short stature (defined as a height 2 standard deviations below the mean for the child's age and sex) who have GHD, poor growth due to renal failure, Turner syndrome, or Prader-Willi syndrome, and for children small for gestational age (children who at birth were 2 standard deviations below the mean for weight or length or both who maintain a small body size beyond the age of 2 years)⁵⁷ and for idiopathic short stature⁵⁸ (defined as height 2.25 standard deviations below the mean for age and sex, or the shortest 1.2% of children).^{16, 59}

As stated earlier, in adults the FDA has stated that distribution of hGH is legal for only 3 conditions: wasting syndrome of AIDS (this does not include lipodystrophy⁶⁰), short bowel syndrome and AGHDS. AGHDS must meet 2 diagnostic criteria¹²: biochemical diagnosis of adult GHD by means of a subnormal response to the standard growth hormone stimulation test (peak GH, <5.0 ng/L); and the demonstration of a pathological cause of the poor response such as pituitary disease, hypothalamic disease, surgery, radiation therapy, or trauma or patients who were GH deficient during childhood. Only 1 case per 10,000 adults per year meet these criteria for the diagnosis of GHD; 3 cases per 10 000 also include adults who received GH treatment as children.¹¹

Also, as earlier stated, in January 2007, the FDA released an alert stating unambiguously that anti-aging, body-building and athletic enhancement are not approved indications for hGH, that importation of foreign and unapproved hGH for compounding or distribution in the U.S. is illegal, and that physician prescribing of hGH for an unapproved purpose is part of the distribution chain of hGH and is therefore also illegal.⁶¹

Measurement of IGF-1 levels (a claimed proxy for GH levels) in older adults, when demonstrated to be lower than that of young adults, does not constitute a scientific^{16, 62} or legally¹² accepted diagnosis of AGHDS.

Among all the Dr. M patient records I reviewed, a stimulation test was not performed, and in most cases, the patients were in good physical condition without any evidence provided of pituitary gland pathology. Clinics in general would never perform such a test because in almost all cases the test would not support the legal distribution of hGH.

2. Distribution and administration of compounded hGH (an unapproved drug). There is no documentation as to why Dr. M has chosen to administer and distribute compounded HGH (with B12) to his patients, rather than hGH alone. His pivotal role in the distribution of an unapproved drug to a patient may violate Federal law. The FDA considers distribution of compounded hGH as distribution of an unapproved drug. This is clearly stated in the case of importing hGH for the purpose of compounding in an FDA alert.¹³ Portions of that alert state the following:

Section 303(e) (1) of the FDCA, 21 U.S.C. § 333(e) (1), prohibits knowingly distributing, or possessing with the intent to distribute, HGH for any use in humans other than the treatment of a disease or other recognized medical condition, where such use has been authorized by the Secretary of Health and Human Services (HHS) under section 505 of the FDCA (21 U.S.C. § 355) and pursuant to the order of a

physician. The Secretary of HHS has not authorized, for example, any HGH use for anti-aging, bodybuilding, or athletic enhancement. Thus, distributing, or possessing with the intent to distribute, HGH for these uses or any other unapproved use violates section 303(e) (1) of the FDCA. A violation of section 303(e)(1) carries up to 5 years imprisonment and fines and, if the offense involves an individual under the age of 18 years of age, up to 10 year imprisonment and fines.

HGH products are new drugs and cannot be legally marketed in the U.S. without an approved application. The few HGH products that have been approved for sale by FDA are sold either in liquid form or as lyophilized powders that are labeled for reconstitution by the health care professionals who dispense them. Accordingly, FDA considers both imported HGH lyophilized powder products and liquid HGH products to be finished dosage form drugs, not APIs. Unless these products are the subject of approved new drug applications, they violate section 505 of the FDCA, 21 U.S.C. § 355, and may not be legally imported into the U.S.

Some HGH marketers may claim that their HGH drug products are intended for use in pharmaceutical compounding. These drugs should be evaluated on a case-by-case basis considering the factors in FDA Compliance Policy Guide, section 460.200, and the specific prohibitions set forth in section 303(e) of the FDCA, 21 U.S.C. § 333(e).

HGH intended for pharmacy compounding should be reviewed on a case-by-case basis. Consistent with its Compliance Policy Guide on human drug compounding and the prohibitions set forth in section 303(e) of the Act, 21 U.S.C. § 333(e), FDA may exercise its enforcement discretion in certain instances to allow the importation of HGH for use in traditional pharmacy compounding. In general, FDA should exercise its enforcement discretion only in those instances where (1) the compounded product is intended for a use that has been authorized by FDA for HGH under section 505 of the FDCA; and (2) the drug will be compounded to meet the individual medical needs of a specific patient who cannot be treated with an FDA-approved HGH drug product (e.g., the patient is allergic to the commercially available FDA-approved HGH product).

4. Violating Federal Trade Laws. Common marketing practices regarding GH and related products may also be illegal. In a recent case brought before the US District Court by the Federal Trade Commission (FTC) regarding a defendant selling products claimed to contain GH, the FTC stated several claims that illustrate findings that can lead to fines and disciplinary action⁶³:

1. "The dissemination of false advertisement for the purpose of inducing the purchase of a drug or device pursuant to 15 USC § 52(a) is an unfair or deceptive practice within the meaning of 15 USC § 45(a)."
2. "The defendant deceptively promotes and sells HGH products with claims that are wholly false and cannot be substantiated."
3. "The defendant's claims are false and cannot be substantiated with competent scientific

General Observations from the Two Other Anti-Aging Clinics That I Reviewed

Perhaps one of the most disturbing observations to be made regarding my review of medical records from these clinics was how little information they contained. In some instances there was only a minimal amount of laboratory data accompanying the prescriptions and demographic information. In other cases, it appears that the patient was never seen by the doctor and minimal data were collected by office staff. Making matters much worse was that this inadequate evaluation and oversight is in the context of providing growth hormone, multiple anabolic steroids, and other drugs with potential and potent adverse effects. Follow-up visit documentation was practically nonexistent and some of the patients were not seen again after receiving their drugs so it is impossible to know who sustained harm from the growth hormone and other drugs.

It was clear that the majority of patients were coming to the clinics for body building despite statements by the doctors that they were there for anti-aging. Most of the patients came to the clinics in excellent health with active exercise regimens. All the patients received prescriptions for hGH without appropriate workup or evidence for Adult Growth Hormone deficiency Syndrome. The distribution of anabolic steroids and growth hormone for the patients I reviewed fell completely outside the standard of medical care and as in the case of Dr. M, above, I found numerous and repeated instances of both professional and ethical misconduct as well as violations of both Arizona state and Federal laws particularly with regard to the distribution of growth hormone and anabolic steroids.

Human Growth Hormone Distribution in the United States Resembles a Narcotics Trafficking Ring

Recent high profile cases have revealed a network of anti-aging clinics and compounding pharmacies violating the law with regard to the distribution of hGH. In 2007, Pfizer Pharmaceuticals was fined \$34 million for promoting hGH as an anti-aging and athletic enhancing intervention;⁶⁴ Specialty Services

Distribution, Inc. was fined \$10 million for distributing hGH for athletic enhancement, cosmetic, or anti-aging uses;⁶⁵ the FDA, DEA, and FBI conducted crackdowns (Operation Phony Pharm⁶⁶ and Operation Raw Deal⁶⁷) on national and international trafficking in anabolic steroids and hGH; and Operation "Which Doctor" led to the prosecution of doctors being paid by pharmacies to write prescriptions for hGH without having ever seen the patients.⁶⁸ Despite these actions, the use of hGH remains pervasive and staunchly defended by the anti-aging industry.

As an illustration of how profitable illegal sales of hGH have become, consider the single example of Lowen's Compounding Pharmacy, recently investigated by the New York State Bureau of Narcotic Enforcement. The investigation revealed that the pharmacy would purchase 25 grams of imported hGH for \$75,000; convert each gram into 3,000 IU's of hGH; then sell the drug for \$6 to \$18 per IU, -- netting a profit of \$375,000 to \$1.34 million dollars.⁶⁹ In that raid, narcotics officials seized 90 grams of hGH powder worth \$7.2 million, including a shipment destined for The Health and Rejuvenation Center, an anti-aging clinic in Palm Beach Gardens, Florida.⁷⁰

In the case of the M anti-aging clinic that I described above, the DEA seized 75 vials (6-7 mg/vial) of human growth hormone. Among the patient records I reviewed, all the patients were prescribed and sold, on the anti-aging clinic premises, 1-3 month supplies of growth hormone along with alcohol swabs and syringes. Dosing ranged from .6u to 4 units per day, 6 to 7 days a week. Vials were sold to patients in batches, from 5-15 vials at a time at \$280 per vial. From other documents found by the DEA, it appears Dr. M purchased the growth hormone from a compounding pharmacy for about \$90 a vial, turning a profit of \$190 per vial.

An important feature of hGH distribution for anti-aging and body building is that the vast majority of users pay out-of-pocket for the drug. As a result of these cash-only transactions and the fact that hGH is often misbranded (e.g. illegally imported or made into a "new drug" by combining hGH with another compound⁷¹), the actual number of people receiving hGH as part of an anti-aging treatment regimen is likely to be much higher than a previous estimate of 30,000 users.⁷² If one compounding pharmacy has been caught with 270,000 IU of hGH, as in the case of the Lowen's Pharmacy raid, and a weekly regimen for a single patient ranges from 2-10 IU per week, then it is reasonable to assume, given the hundreds of clinics where hGH is available and hundreds of websites and pharmacies that advertise the drug, that previous estimates of the number of illicit users of hGH for anti-aging and athletic enhancement or body building, combined, is profoundly underestimated.

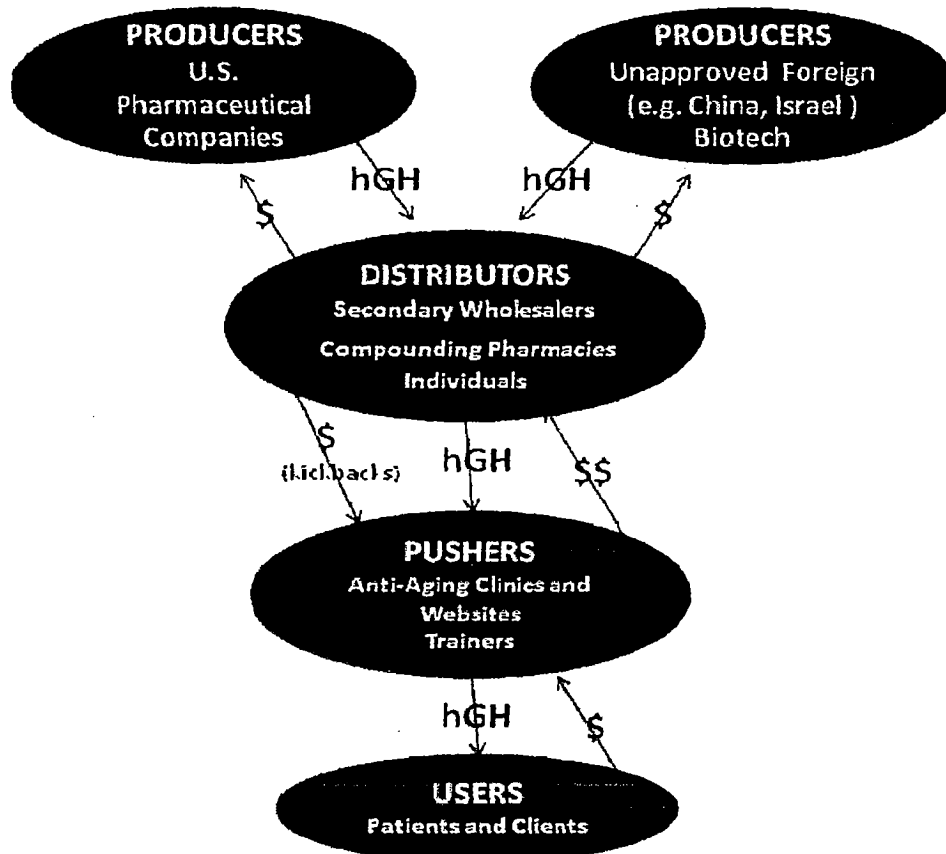


Fig. 2 The growth hormone trafficking ring: The cash-only business of websites or clinics working closely together with compounding pharmacies to turn huge profits⁷³, the national and international anti-aging and age-management organizations assisting in and facilitating the marketing of the growth hormone for anti-aging, and drug companies turning a blind eye to how and to whom their product is distributed bear similarity to what some investigative reporters have likened to a narcotics trafficking ring.^{74, 75}

Another consequence of a cash-only business is that there is no independent means to detect and monitor adverse events. People who might have experienced side effects may simply stop taking the drug and end their relationship with the website or clinic without reporting the problem, especially when the side effects are reversible. If hGH caused more severe health consequences, including cancer and death, there is little incentive for clients to pursue legal action when causation is difficult to prove, or because clients are often required to sign contracts that absolve the provider of any potential wrongdoing. Finally, there is an explicit disincentive for anti-aging practitioners to report adverse experiences with hGH.⁷⁶

In summary:

The reemergence of the health and longevity salesman has exploded on the heels of growth hormone. Just the name "growth hormone" invokes visions of the fountain of youth. Thus, with deceptive marketing and unethical physicians who wield inappropriate influence over their patients, illegal and dangerous growth hormone distribution has become pervasive. Likely somewhere in the range of currently 200,000 Americans have been misled to believe in the purported magical powers of growth hormone, whether they be anti-aging, body building or injury repairing. Profits from the sale of growth hormone, particularly at the level of secondary wholesalers and compounding pharmacies rival if not better those seen in the crack cocaine trade. With such outrageous profits, hundreds of unscrupulous doctors and businesses are willing to take the risk of illegally prescribing and distributing growth hormone. Profits are set aside for intimidating lawyers and deceptive lobbying and marketing campaigns to keep the industry alive, growing and safe for its producers, distributors, pushers and users.

Experts in the care of patients with true growth hormone-related problems clearly state that giving growth hormone for anti-aging or age-management or body building is not medically appropriate particularly when weighing the high risk to benefit ratio.^{6,7,16}

Thus, in terms of law enforcement and sentencing guidelines, the focus of attention should be on the producers and distributors. Because of sophisticatedly deceptive and widespread marketing practices and in the case of clinics, the unusual power a doctor can have over a patient, the users seem to be more the victims. Herein lies, in my opinion, the reason why sentencing guidelines for growth hormone-related offenses must be strong and intimidating: to protect the public from this highly unethical industry that bilks its victims out of tens of thousands of dollars and in many cases exposes them to unnecessary and potentially serious harm. In fact, the current laws pertaining to growth hormone really pertain to the drug's distribution, and not its possession by users.

Recommendations**Responses to Specific Issues For Comment**

1. How human growth hormone (hGH) should be quantified under §2D1.1 (Unlawful Manufacturing, Importing, Exporting, or Trafficking (Including Possession with Intent to Commit These Offenses)).

Most growth hormone appears to be distributed as a lyophilized powder and it is therefore generally measured as a weight. Supporting the use of weight (mg) is the fact that most sales of GH between producers and distributors are based on weight.

Clients or patients will often be instructed to inject themselves with a specific volume of growth hormone solution (powder reconstituted with water) of a particular concentration. However, by knowing the concentration of growth hormone in solution, these volumes can of course still be converted to mg amounts of growth hormone. Even if a quantity of growth hormone is expressed on the vial as some number of international units, one can use the conversion rate of 2.7 IU per mg growth hormone to determine the weight.

2. The existing definition of "unit" applies to trafficking in steroids, which is a Schedule III controlled substance with a penalty scheme similar to distribution offenses involving human growth hormone (hGH). The Commission requests comment regarding the harmfulness of hGH offenses relative to steroid offenses. Are hGH trafficking offenses more harmful, less harmful, or approximately equal in harm? Based on that comparison, what quantity of vials, IU, or mg of hGH should be used to determine a "unit" for purposes of calculating the base offense level (e.g., one vial, 3 IUs, 1 mg)?

In reviewing the medical records from anti-aging clinics and reading the blogs of body-building sites, I have almost never seen growth hormone given in isolation. It is almost always given in conjunction with one or more anabolic steroids (e.g. testosterone, nandrolone etc) whether the intended illegal purpose be anti-aging, body-building or athletic enhancement. From my review of Dr. M's medical records, the severity and rate of harmful side effects and the potential for harm to the patient for the typical doses of growth hormone and testosterone are approximately similar. Of significant concern is the possibility that growth hormone and testosterone may be additive in promoting certain severe and perhaps life threatening diseases such as obstructive sleep apnea and cancer. For these reasons, it would make sense for growth hormone offenses to be similar to anabolic steroids in terms of calculating the base offense level.

My understanding is that The Drug Equivalency Table under **§2D1.1** establishes one unit of a Schedule III substance to be equivalent to one gram of marijuana. A unit of anabolic steroid is 10 cc or 50 pills. In the case of the clinics I reviewed, a usual dose of testosterone cypionate was about 1 cc of about 200 mg/cc once per week. Thus, in this case, a 10 dose supply or 2 grams of testosterone would equal a gram of marijuana. If one assumes the usual starting dose of growth hormone in an anti-aging clinic to be 0.25

mg (about 0.25 cc of a 6 mg/6cc vial), then 10 doses would be 2.5 mg. Thus, in terms of equivalency to testosterone, in terms of dosing, cost and potential harm, it would make sense to me that **2.5 mg lypholyzed growth hormone would = 1 Unit.**

In the Drug Quantity Table, **§2D1.1** offenders responsible for 40,000 or more units of Schedule III substances receive a maximum base offense level of 20. Using the above reasoning, 40,000 units of growth hormone would equal 100,000 mg or 100 grams of growth hormone.

To place this amount in perspective, the amount of growth hormone seized in the Lowen's Pharmacy case was 90 grams of hGH powder (translating into level 18) worth \$7.2 million, some of which was destined for The Health and Rejuvenation Center, an anti-aging clinic in Palm Beach Gardens, Florida.⁷⁰

In Dr. M's case, 75 vials, or about 450 mg (which he bought for about \$90 and sold for \$330 per vial) worth \$24,750 450 mg, were found in his clinic and seized by the DEA. 450 mg would equal 180 units and lead to an offense level of 6.

To me, the level offense of 18 makes sense in the case of the amount of growth hormone seized in the Lowen's Pharmacy case, particularly in light of the maximum sentence (without enhancements) stipulated by Congress. Regarding the case of Dr. M, a number of enhancements (suggested below, question #5) would increase the offense level to a point that incarceration would be considered.

3. The Commission requests comment regarding whether a maximum base offense level should apply in §2D1.1 for an offense involving the distribution of human growth hormone (hGH). For certain types of controlled substances, the marijuana equivalencies in the Drug Equivalency Table in §2D1.1 are "capped" at specified amounts. For example, anabolic steroids and other Schedule III controlled substances, which also have a statutory maximum of 5 years' imprisonment, are subject to a maximum base offense level of 20. Should the Commission similarly provide a maximum base offense level for offenses involving the distribution of hGH and, if so, what maximum base offense level should apply?

My understanding of the law stipulates a maximum of 5 years and a maximum fine of \$250,000 for distribution offenses related to growth hormone and thus the maximum level, without enhancements should be consistent with this. I do feel though that additional enhancements are very important and necessary and I discuss this below.

4. Should the Commission amend the commentary to §2D1.1 in Application note 8 to cover offenses involving human growth hormone (hGH)? Specifically, the enhancement at §2D1.1 (b) (6) defines "masking agent" as "a product added to, or taken with, an anabolic steroid to prevent detection of the anabolic steroid in an individual's body." Masking agents also can be taken to prevent the detection of other controlled substances including hGH. Should the Commission expand the definition of masking agent, and thus application of the enhancement, in a manner that covers hGH?

While I am unaware of agents that can mask use of growth hormone, I don't see any reason why the Commission shouldn't expand the definition to cover hGH.

Human Growth Hormone also may be used to enhance an individual's performance. Should the Commission expand the scope of the enhancement at §2D1.1 (b) (7) pertaining to the distribution to an athlete to cover offenses involving hGH? Application Note 8 instructs the court on how to apply §3B1.3 (Abuse of Position of Trust or Use of Special Skill) in a case in which a coach used his or her position to influence an athlete to use an anabolic steroid. Similarly, a coach may use his or her position to influence an athlete to use hGH. Should the Commission modify Application Note 8 to include cases involving hGH?

Yes, I agree that given the continued desire of those who illegally distribute growth hormone to market the drug to athletes, the scope of enhancement at §2D1.1 (b) (7) pertaining to the distribution to an athlete should cover offenses involving hGH.

Along these lines though, I feel it is very important to point out that given the many anti-aging clinics that now distribute growth hormone, it is likely that athletes represent a minority of those who receive illegally distributed growth hormone. In fact, as pointed out earlier, the FDA, in its January 2007 Alert, clearly pointed out that besides athletic related use, anti-aging and body building are important illegal uses of growth hormone.¹³ Thus, if special note (and level enhancements) is to be made for coaches who use their position to influence an athlete's use of growth hormone, the cases of physicians illegally distributing growth hormone, who likewise can have disproportionate and convincing influence over their patients, should also receive specific attention for using such influence to their benefit. Mention of only the coach-athlete relationship may provide the impression that the unethical use of power by a doctor over his or her patient in order to sell and distribute growth hormone is less important, so hopefully specific mention of physicians can be made here.

I believe application of U.S.S.G. § 3B1.3 (Abuse of Position of Trust or Use of Special Skill)⁷⁷ can address a physician's abuse of power, as in the sentencing of Dr. Shortt who received a two-level enhancement for his use of the special skill as a doctor.⁷⁸

In a particularly egregious example, in my review of DEA seized anti-aging clinic medical records, I read instances of the doctor continuing growth hormone in patients (and continuing to make more money) who experienced new elevated blood sugars, elevated blood pressure or upper extremity swelling, despite concerns voiced by the patients.

5. The Commission requests comment regarding whether §2N2.1 (Violations of Statutes and Regulations Dealing with Any Food, Drug, Biological Product, Device, Cosmetic or Agricultural Product) adequately addresses numerous statutes referenced to that guideline. The statutes referenced to §2N2.1 prohibit conduct ranging from regulatory offenses with a statutory maximum of 1 year imprisonment (e.g. 21 USC §643 record keeping requirements) to violations of the Prescription Drug Marketing Act of 1987 that carry a statutory maximum penalty of 10 years imprisonment. Should the Commission provide alternative base offense levels, specific offense characteristics identifying aggravating factors warranting an enhanced sentence, or some combination of these to more adequately address these offenses? If so, what should be the offense levels associated with alternative base offense levels and/or specific offense characteristics?

The Commission is very wise to consider the changing landscape and variations of not just illegal growth hormone distribution, but also, I would argue, it needs to do the same for anabolic steroids. Growth hormone and anabolic steroids are no longer distributed and sold to users in back alleys and locker rooms. As illustrated in the above Figure 2, brazen and very wealthy narcotics-like trafficking rings are operating in broad daylight. The black market for extra doses of Serostim sold by sufferers of AIDS wasting syndrome is no longer necessary. Taj Mahal like anti-aging clinics (e.g. Cenegenics^{79, 80} in Las Vegas and Florida) and Beverly Hills doctors⁸¹ appear on television shows such as 60 minutes and Anderson Cooper 360 professing the longevity enhancing wonders of growth hormone. Thus, just about anyone can walk into any one of hundreds of anti-aging clinics across the country and purchase vials of growth hormone and testosterone, be taught how to inject the drugs and then take the lot home to inject on their own. There are also at least hundreds of websites selling growth hormone, many without ever arranging for a physician to see the patient and some which pay physicians to write prescriptions without ever seeing or even speaking with the patient. This new environment for distributing growth hormone merits a number of special considerations in sentencing:

(1) Numerous clinics and obviously websites market their services including growth hormone "replacement" on the internet and at times via other media such as newsletter advertisements, and radio and magazine features. Perhaps this can be addressed by §2D1.1(b)(5): "Distribution of a controlled substance through mass-marketing by means of an interactive computer service leads to a two-level-enhancement."⁸² Also pertaining to such advertising is 21 U.S.C. § 843(b): §2D1.6. Use of Communication Facility in Committing Drug Offense; Attempt or Conspiracy."

I agree with suggestions by the FDA:

(2) "Add 21 U.S.C. § 333(e)(2) - distribution of HGH to a person under 18 years of age - to the § 2D1.2 Guideline, which presently applies to controlled substance offenses involving protected locations (e.g., schools) or pregnant or underage persons."

(3) "Add an application note to § 2N2.1 to include substantial risk of bodily harm as a basis for upward departure."

and

(4) "for criminal offenses involving misbranded or adulterated products where "loss" is relevant to the sentence to be imposed, loss should be determined by calculating the full amount paid (by consumers and others) for the adulterated or misbranded product, without any deduction or subtraction for the value of the product." My understanding is that this could apply to doctors, compounding pharmacies or other distributors who sell illegally imported growth hormone (eg jinropin) or an adulterated version of growth hormone such as compounded cyanobalamin-B12.

(5) Given the brazen attitudes of those who openly and deceptively advertise growth hormone for anti-aging, body-building or other non-approved uses, and make it so easy for patients to obtain the drug by providing free-standing clinics, I suggest that physicians and others who illegally distribute growth hormone out of offices or clinics be regarded as managing a drug establishment for example as in **§2D1.8. Renting or Managing a Drug Establishment; Attempt or Conspiracy** (Statutory Provision: 21 U.S.C. § 856). Per the Sentencing Commission's guidelines, "*This section covers the offense of knowingly opening, maintaining, managing, or controlling any building, room, or enclosure for the purpose of manufacturing, distributing, storing, or using a controlled substance contrary to law (e.g., a "crack house").*" In the context of reasons for other level enhancements, an offense level enhancement of 2 levels appears appropriate to me. In the case of clinic chains, where an offender owns and manages

multiple clinics, one should consider the level enhancement per each establishment up to some maximum.

Additional considerations for level enhancements:

- (6) Engaging in monetary transactions over \$10,000 per patient per year
- (7) Physical or mental harm to a patient resulting from illegally distributed growth hormone
- (8) Contracting with a person to provide a testimonial, either public or private
- (9) Receiving money or gifts of any form from a distributor of what will ultimately be illegally distributed growth hormone in exchange for a patient's or client's purchase of that growth hormone
- (10) Providing money or gifts to others who refer patients or clients that ultimately receive illegally distributed growth hormone
- (11) Inadequate record keeping, including the omission of major components of a medical record such as history of present illness, physical examination, assessment and plan, laboratory results, and/or medical justification for the administration of growth hormone.
- (12) No intent by the physician to see the patient again, once they have received illegally distributed growth hormone
- (13) Never seeing the patient
- (14) interstate commerce (eg mailing illegally distributed growth hormone to out-of-state clients or patients)
- (15) Two level enhancement for creating a reckless risk of bodily injury to clients or patients. Increasingly greater levels for, respectively, actual reversible harm, permanent harm, or death.
- (16) Two level enhancement for illegally distributing growth hormone to 10-49 patients within a single year and a three level enhancement for doing so for 50-99 patients and a four level enhancement in the case of >100 patients in a single year.
- (17) Disseminating literature, books, brochures, other forms of media that claims administration of growth hormone slows or reverses or helps to slow or reverse aging and age-related diseases, syndromes and/or problems.

REFERENCES

- [1] Perls TT, Reisman NR, Olshansky SJ. Provision or distribution of growth hormone for "antiaging": clinical and legal issues. *JAMA*. 2005;**294**(16): 2086-2090.
- [2] Rothenberg R, Becker K. . *Forever Ageless*. Encinitas: California Healthspan Institute, 2001.
- [3] Somers S. *Ageless: The Naked Truth About Bioidentical Hormones*. New York: Crown, 2006.
- [4] Perls T. Anti-aging quackery: Human growth hormone and tricks of the trade -more. dangerous than ever. *J Gerontology: Biological Sciences* 2004;**59A**: 682-691.

- [5] Perls TT, Reisman NR, Olshansky SJ. Provision or distribution of growth hormone for "antiaging": clinical and legal issues. *JAMA*. 2005;**294**: 2086-2090.
- [6] Melmed S. Supplemental growth hormone in healthy adults: the endocrinologist's responsibility. *Nature clinical practice*. 2006;**2**: 119.
- [7] Vance ML. Can growth hormone prevent aging? *N Engl J Med*. 2003;**348**: 779-780.
- [8] In 1988 and again in 1990, Congress amended the Food, Drug, and Cosmetic Act (FDCA) to enact more stringent controls with higher penalties for offenses involving the distribution of anabolic steroids and HGH [codified at 21 USC §333(e)(1)]. In 1993, the provisions outlawing the distribution of specifically growth hormone were recodified as 21 USC §333(f) (pursuant to PL No. 103-80, §3(e), 107 Stat 775).
- [9] Title 4, (Civil) Resource Manual. . United States Attorneys' Manual. 19 Human Growth Hormone/Steroids Statutory Overview. US Department of Justice Website. Available at: http://www.usdoj.gov/usao/eousa/foia_reading_room/usam/title4/civ00019.htm. Accessibility verified January 7, 2005 and September 30, 2007. 1998.
- [10] United States Code. Title 21: Food and Drugs CFF, Drug, and Cosmetic Act, Subchapter III: Prohibited Acts and Penalties, Sec. 333. Penalties. GPO Access Web site. Available at: http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=browse_usc&docid=Cite: 21USC333. January 7, 2003. Accessibility verified September 21, 2005 and September 30, 2007.
- [11] Pugeat M. Advances in growth hormone therapy: a new registry tool. *Horm Res*. 2004;**62**(suppl 4): 2-7.
- [12] Tran D. FDA warning letter to Genentech Inc concerning promotional materials for Neutropin. *US Department of Health and Human Services Web site* Available at: <http://www.fda.gov/cder/warn/2003/11522pdf> August 25, 2003 Accessibility verified September 21, 2005.
- [13] FDA Alert, IA #66-71, 1/23/07, "IMPORT ALERT #66-71, "DETENTION WITHOUT PHYSICAL EXAMINATION OF HUMAN GROWTH HORMONE (HGH), ALSO KNOWN AS SOMATROPIN". URL: http://www.fda.gov/ora/fiars/ora_import_ia6671.html. Section 303(e) (1) of the FDCA, 21 USC 333(e) (1), prohibits knowingly distributing, or possessing with the intent to distribute, HGH for any use in humans other than the treatment of a disease or other recognized medical condition, where such use has been authorized by the Secretary of Health and Human Services (HHS) under section 505 of the FDCA (21 USC 355) and pursuant to the order of a physician. The Secretary of HHS has not authorized, for example, any HGH use for anti-aging, bodybuilding, or athletic enhancement. Thus, distributing, or possessing with the intent to distribute, HGH for these uses or any other unapproved use violates section 303(e) (1) of the FDCA. A violation of section 303(e)(1) carries up to 5 years imprisonment and fines and, if the offense involves an individual under the age of 18 years of age, up to 10 years imprisonment and fines.
- [14] PR Newswire. Is growth hormone replacement illegal in deficient adults? URL: <http://www.mywire.com/pubs/PRNewswire/2005/12/21/1122102> Accessed January 12, 2008. December 21, 2005.
- [15] Collins R. Rick Collins. Legal Update: The Practitioner's Guide to Human Growth Hormone and Testosterone Replacement Therapy. **Volume 2008**, 2005.
- [16] Gharib H, Cook DM, Saenger PH, et al. American Association of Clinical Endocrinologists medical guidelines for clinical practice for growth hormone use in adults and children--2003 update. *Endocr Pract*. 2003;**9**: 64-76 URL: <http://www.aace.com/pub/pdf/guidelines/hgh.pdf> Accessed January 12, 2008.
- [17] Genotropin. Genotropin: somatropin [rDNA origin] for injection. **Volume 2007**, 2007.
- [18] Humatrope. Humatrope® Somatropin (rDNA origin) for injection, vials and cartridges. **Volume 2007**, 2007.

- [19] Norditropin. Norditropin® SimpleXx®. **Volume 2007**, 2007.
- [20] Genentech. Prescribing information for Nutropin AQ® [somatropin (rDNA origin) injection]. **Volume 2007**, 2007.
- [21] Saizen. SAIZEN® [somatropin (rDNA origin) for injection], NDA 19-764/S-020. **Volume 2007**, 2004.
- [22] Kwan AY, Hartman ML. IGF-I measurements in the diagnosis of adult growth hormone deficiency. *Pituitary*. 2007;**10**: 151-157.
- [23] Pugeat M. Advances in growth hormone therapy: a new registry tool. *Horm Res*. 2004;**62 Suppl 4**: 2-7.
- [24] Liu H, Bravata DM, Olkin I, *et al*. Systematic review: the safety and efficacy of growth hormone in the healthy elderly. *Ann Intern Med*. 2007;**146**: 104-115.
- [25] Blackman MR, Sorkin JD, Munzer T, *et al*. Growth hormone and sex steroid administration in healthy aged women and men: a randomized controlled trial. *JAMA*. 2002;**288**: 2282-2292.
- [26] Berggren A, Ehrnborg C, Rosen T, Ellegard L, Bengtsson BA, Caidahl K. Short-term administration of supraphysiological recombinant human growth hormone (GH) does not increase maximum endurance exercise capacity in healthy, active young men and women with normal GH-insulin-like growth factor I axes. *J Clin Endocrinol Metab*. 2005;**90**: 3268-3273.
- [27] Giannoulis MG, Sonksen PH, Umpleby M, *et al*. The effects of growth hormone and/or testosterone in healthy elderly men: a randomized controlled trial. *J Clin Endocrinol Metab*. 2006;**91**: 477-484.
- [28] Papadakis MA, Grady D, Black D, *et al*. Growth hormone replacement in healthy older men improves body composition but not functional ability. *Ann Intern Med*. 1996;**124**: 708-716.
- [29] Bonkowski MS, Pamenter RW, Rocha JS, Masternak MM, Panici JA, Bartke A. Long-lived growth hormone receptor knockout mice show a delay in age-related changes of body composition and bone characteristics. *J Gerontol A Biol Sci Med Sci*. 2006;**61**: 562-567.
- [30] Coschigano KT, Holland AN, Riders ME, List EO, Flyvbjerg A, Kopchick JJ. Deletion, but not antagonism, of the mouse growth hormone receptor results in severely decreased body weights, insulin, and insulin-like growth factor I levels and increased life span. *Endocrinology*. 2003;**144**: 3799-3810.
- [31] Suh Y, Atzmon G, Cho M-O, Hwang D, Bingrong L, Leahy DJ, Barzilai N, Cohen P. Functionally significant insulin-like growth factor 1 receptor mutations in centenarians. *Proceedings of the National Academy of Sciences of the United States of America*. 2008;**105**: 3438-3442.
- [32] Smith GD, Gunnell D, Holly J. Cancer and insulin-like growth factor-I. A potential mechanism linking the environment with cancer risk. *BMJ*. 2000;**321**: 847-848.
- [33] Sonntag WE, Lynch CD, Cefalu WT, *et al*. Pleiotropic effects of growth hormone and insulin-like growth factor (IGF)-1 on biological aging: inferences from moderate caloric-restricted animals. *J Gerontol A Biol Sci Med Sci*. 1999;**54**: B521-538.
- [34] Conway-Campbell BL, Wooh JW, Brooks AJ, *et al*. Nuclear targeting of the growth hormone receptor results in dysregulation of cell proliferation and tumorigenesis. *Proc Natl Acad Sci U S A*. 2007;**104**: 13331-13336.
- [35] Klatz R. A4M Official Response Statement, Issued January 15. **Volume 2007**, 2007.
- [36] Russell SJ, Kahn CR. Endocrine regulation of ageing. *Nature reviews*. 2007;**8**: 681-691.
- [37] Perls TT. Anti-aging quackery: human growth hormone and tricks of the trade--more dangerous than ever. *The journals of gerontology*. 2004;**59**: 682-691.
- [38] Mattingly D, Estrada I. HGH in forefront to remain young. URL: <http://www.cnn.com/2008/HEALTH/01/24/mattingly.hgh/?iref=mpstoryview>. Accessed January 24, 2008.

[39] Assuming people pay on average, \$10,000 per year for GH, \$2 billion people would mean at least 200,000 customers. This is a very conservative figure since few individuals stay with a hormone replacement program for more than a few months.

[40] Kwan AY, Hartman ML. IGF-I measurements in the diagnosis of adult growth hormone deficiency. *Pituitary*. 2007;**10**: 151-157.

[41] Ho KK, 2007 GH Deficiency Consensus Workshop Participants. Consensus guidelines for the diagnosis and treatment of adults with GH deficiency II: a statement of the GH Research Society in association with the European Society for Pediatric Endocrinology, Lawson Wilkins Society, European Society of Endocrinology, Japan Endocrine Society, and Endocrine Society of Australia. *Eur J Endocrinol* 2007;**157**: 695-700 URL: <http://www.eje-online.org/cgi/content/full/157/696/695>.

[42] Arizona State Legislature, 32-1401. Definitions. 27. "Unprofessional conduct" includes the following, whether occurring in the state or elsewhere: (ff) Knowingly or failing to disclose to a patient on a form that is prescribed by the board and that is dated and signed by the patient or guardian acknowledging that the patient or guardian has read and understands that the doctor has a direct financial interest in a separate diagnostic or treatment agency or in nonroutine goods or services that the patient is being prescribed and if the prescribed treatment, goods or services are available on a competitive basis. This subdivision does not apply to a referral by one doctor of medicine to another doctor of medicine within a group of doctors of medicine practicing together.

[43] Arizona, Medical Board. The Arizona Medical Board's Guidelines For Physicians Who Incorporate Or Use Complementary Or Alternative Medicine In Their Practice. ? year URL:

<http://www.azmd.gov/Alternative%20Medicine/Alternative%20Medicine%20in%20Physician%20Practice.pdf>. , pp. Some physician practices have begun selling healthcare related products directly to patients.

The law does not directly prohibit this practice, but any fraud or misrepresentations would violate the Medical Practice Act. Due to the potential for conflicts of interests, however, physicians should not sell, rent or lease health-related products or engage in exclusive distributorships and/or personal branding. If a physician chooses to make products directly available to patients, the physician must disclose to the patient that the physician has a financial interest in the goods or services.

[44] Hammer Institute for Anti-Aging Medicine, Advertisement Brochure.

[45] Arizona State Legislature, 32-1401. (mm) The representation by a doctor of medicine or the doctor's staff, employer or representative that the doctor is boarded or board certified if this is not true or the standing is not current or without supplying the full name of the specific agency, organization or entity granting this standing. Definitions. 27. "Unprofessional conduct" includes the following, whether occurring in the state or elsewhere.

[46] Arizona State Legislature, 32-1401. . Definitions. 27. "Unprofessional conduct" includes the following, whether occurring in the state or elsewhere: (bb) Representing or holding oneself out to being a medical specialist when such is not the fact.

[47] Trespicio T, (ttrespicio@earthlink.net). The Hammer Institute for Anti-Aging Medicine. *Phoenix MD News*, September 2005.

[48] Arizona, Medical Board. The Arizona Medical Board's Guidelines For Physicians Who Incorporate Or Use Complementary Or Alternative Medicine In Their Practice. URL:

<http://www.azmd.gov/Alternative%20Medicine/Alternative%20Medicine%20in%20Physician%20Practice.pdf>: In advertising a practice or while consulting with a patient, a physician may not make false or fraudulent claims. A physician may not claim that a particular treatment can cure, alleviate or

ameliorate a disease or condition unless the claim is supported by valid, conventional science. A physician's personal experience, patient testimony and other anecdotal evidence is not sufficient evidence to support a claim of a treatment's efficacy and safety. A physician may, however, inform the patients of his/her experiences with using a particular treatment. When advising patients on treatment

options, a physician must disclose to the patient the physician's basis for making claims of the efficacy and safety of a particular treatment.

[49] Mayo, Clinic Staff. Testosterone therapy: The answer for aging men? *Mayo Clinic Website* URL: <http://www.mayoclinic.com/health/testosterone-therapy/MC00030> accessed November 10, 2007.

[50] Wald M, Meacham RB, Ross LS, Niederberger CS. Testosterone replacement therapy for older men. *Journal of Andrology*. 2006;**27**: 126-133.

[51] Hammer Institute for Anti-Aging Medicine, Advertisement (one page).

[52] Liu H, Bravata DM, Olkin I, et al. . Systematic review: the safety and efficacy of growth hormone in the healthy elderly. *Ann Intern Med* 2007;**146**: 104-115.

[53] Arizona, Medical Board. The Arizona Medical Board's Guidelines For Physicians Who Incorporate Or Use Complementary Or Alternative Medicine In Their Practice. ? year URL: <http://www.azmd.gov/Alternative%20Medicine/Alternative%20Medicine%20in%20Physician%20Practice.pdf>. : The treatments offered should, at a minimum:

- have a favorable risk/benefit ratio compared to other treatments for the same condition;
- be based upon a well founded expectation that it will result in a favorable patient outcome, including preventive practices; and
- be based upon the expectation that a greater benefit will be achieved than can be expected with no treatment.

The physician should consider treatments that are safe and demonstrably effective first when developing a treatment plan. The use of unsafe and not demonstrably effective treatments is experimental in nature and a physician who wishes to use such a treatment should only do so under rigidly controlled conditions that meet all State and National standards and protocols for research including submission of the proposed treatment to an Institutional Review Board for approval.

[54] Arizona State Legislature, 32-1401. Definitions. 27. "Unprofessional conduct" includes the following, whether occurring in this state or elsewhere: (j) Prescribing, dispensing or administering any controlled substance or prescription-only drug for other than accepted therapeutic purposes.

[55] Arizona State Legislature, 32-1401. Definitions. 27. "Unprofessional conduct" includes the following, whether occurring in the state or elsewhere: (y) The use of experimental forms of diagnosis and treatment without adequate informed patient consent, and without conforming to generally accepted experimental criteria including protocols, detailed records, periodic analysis of results and periodic review by a medical peer review committee as approved by the FDA or its successor agency.

[56] Arizona State Legislature, 32-1401. Definitions 27 "Unprofessional conduct" includes the following: (mm) The representation by a doctor of medicine or the doctor's staff, employer or representative that the doctor is boarded or board certified if this is not true or the standing is not current or without supplying the full name of the specific agency, organization or entity granting this standing.

[57] de Zegher F, Hokken-Koelega A. Growth hormone therapy for children born small for gestational age: height gain is less dose dependent over the long term than over the short term. *Pediatrics*. 2005;**115**: e458-e462.

[58] FDA approves Humatrope for Short Stature. Available at: <http://www.fda.gov/bbs/topics/ANSWERS/2003/ANS01242.html>. July 25, 2003. Accessibility verified September 21, 2005. FDA Talk Paper. US Food and Drug Administration Web site. .

[59] Wilson TA, Rose SR, Cohen P, et al. Update of guidelines for the use of growth hormone in children: the Lawson Wilkins pediatric endocrinology society drug and therapeutics committee. *J Pediatr*. 2003;**143**: 415-421.

[60] Roehr B. The many faces of human growth hormone. *BETA*. 2003;**15**: 12-16.

- [61] Food and Drug Administration. Import alert #66-71, "Detention without physical examination of human growth hormone (HGH), also known as somatropin". 2007;URL: http://www.fda.gov/ora/fiars/ora_import_ia6671.html.
- [62] Aimaretti G, Corneli G, Rovere S, et al. Insulin-like growth factor I levels and the diagnosis of adult growth hormone deficiency. *Horm Res.* 2004;**62**(suppl 1): 26-33.
- [63] Federal Trade Commission vs Creaghan A. Harry, Individually and Doing Business As Hitech Marketing, Scientific Life Nutrition and Rejuvenation Health Corp. United States District Court for the Northern District of Illinois Eastern Division Web site. Case 04C 790. Available at: <http://www.ftc.gov/os/caselist/0423085/040729memo0423085.pdf>. July 28, 2004. Accessibility verified September 22, 2005.
- [64] United States Attorney's Office. U.S. Department of Justice Press Release, State of Massachusetts. Pfizer Subsidiary Agrees to Plead Guilty for Offering Kickback and Pay \$19.68 Million Criminal Fine; Second Subsidiary Agrees to Pay Additional \$15 Million Penalty to Resolve Allegations of Illegal Promotion of Human Growth Hormone., **Volume 2007**, April 2, 2007.
- [65] United States Attorney's Office. United States Attorney's Office, State of Massachusetts Press Release. Express scripts subsidiary agrees to deferred prosecution for illegal distribution of human growth hormone., **Volume 2007**, 2007.
- [66] U.S. Department of Justice Press Release, U.S. Attorney's Office, Connecticut. Operation Phony Pharm: six charged as a result of investigation targeting internet sale of steroids, human growth hormone., **Volume 2007**, 2007.
- [67] U.S. Department of Justice, U.S. Drug Enforcement Agency. Press release. DEA Announces Largest Steroid Enforcement Action in U.S. History Raw steroid materials from China, HGH, Insulin Growth Factor, counterfeit medications also part of Operation Raw Deal., **Volume 2007**, September 24, 2007.
- [68] Office of the Albany County District Attorney. Operation Which Doctor. **Volume 2007**, 2007.
- [69] Quinn T. Inside a steroid bust. Daily News takes you along for the ride. Daily News., **Volume 2007**, May 13, 2007.
- [70] Assael S. Raid in Brooklyn nets more than \$7 million in growth hormone. ESPN The Magazine., **Volume 2007**, 2007.
- [71] Food and Drug Administration. Import alert #66-71, "Detention without physical examination of human growth hormone (HGH), also known as somatropin". URL: http://www.fda.gov/ora/fiars/ora_import_ia6671.html Accessed January 12, 2008. 2007. .
- [72] Langreth R. Langreth, R. Sweet syringe of youth **Volume 2007**: Forces.com website, December 11, 2000.
- [73] Operation Which Doctor, URL: http://www.albanycountyda.com/owd/which_doctor.htm.
- [74] Dunn S. Greeley Doctors Implicated in Illegal Steroid Ring *Greeley Tribune, Colorado*. January 26, 2008.
- [75] Lyons B. Steroids beyond sports. Celebrities now among those linked to drug shipments *Albany Times Union*. January 13, 2008. URL: <http://timesunion.com/AspStories/story.asp?storyID=654817&category=NATIONAL&BCCode=HOME&newsdate=1/13/2008>.
- [76] Perlis TT. Anti-aging quackery: human growth hormone and tricks of the trade--more dangerous than ever. *J Gerontol A Biol Sci Med Sci.* 2004;**59**: 682-691.
- [77] §3B1.3. , Abuse of Position of Trust or Use of Special Skill. If the defendant abused a position of public or private trust, or used a special skill, in a manner that significantly facilitated the commission or concealment of the offense, increase by 2 levels. This adjustment may not be employed if an abuse of trust or skill is included in the base offense level or specific offense characteristic. If this adjustment is based upon an abuse of a position of trust, it may be employed in addition to an adjustment under

§3B1.1 (Aggravating Role) ; if this adjustment is based solely on the use of a special skill, it may not be employed in addition to an adjustment under §3B1.1 (Aggravating Role) . URL:

http://www.ussc.gov/2003guid/3b1_3.htm.

[78] UNITED STATES of America, Plaintiff-Appellee, v. James M. SHORTT, Defendant-Appellant, United States Court of Appeals, Fourth Circuit. - 485 F.3d 243, Argued February 2, 2007 Decided May 10, 2007 Dr. James M. Shortt pleaded guilty to one count, of a 43-count indictment, charging him with participating in a seven-year conspiracy to distribute and dispense and to cause to be distributed and dispensed anabolic steroids and human growth hormone, in violation of 21 U.S.C. §§ 841(a)(1), 333(e), and 846. URL: <http://64.233.169.104/search?q=cache:-bxKes9FlWJ:cases.justia.com/us-court-of-appeals/F3/485/243/+level+enhancement+%C2%A72D1.1+physician&hl=en&ct=clnk&cd=11&gl=us>.

[79] Cenegenics video, URL: <http://www.youtube.com/watch?v=xwGVGpl3IW0>.

[80] Cenegenics Florida, URL: <http://cbs4.com/video/?id=42545@wfor.dayport.com>.

[81] CNN: HGH in forefront to remain young. January 24 UhwccHmh1h.

[82] United States v. Hanny, 8th Cir. Smith, Circuit Judge 07-1010, December 12, 2007. Distributing controlled substances through mass-marketing by means of an interactive computer service. URL: <http://64.233.169.104/search?q=cache:iVlrKeP9BXUJ:www.law.com/jsp/decisionstate.jsp%3Fid%3D1197540289700+level+enhancement+%C2%A72D1.1+physician&hl=en&ct=clnk&cd=1&gl=us>.

20 FEBRUARY 2008



National Organization of
Parents Of Murdered Children, Inc.
For the families and friends of those who have died by violence.

40 East Eighth Street, Suite B-41 • Cincinnati, OH 45202 • Toll Free: (888) 818-POMC

THE UNITED STATES SENTENCING COMMISSION
ONE COLUMBUS CIRCLE, N.E.
WASHINGTON, DC 20002-8002



510 King Street • Suite 424
Alexandria, VA 22314
703-535-6682

Dear Commission Members:

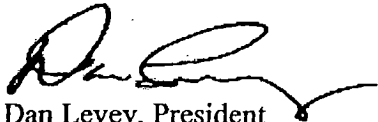
The National Organization for Victim Assistance and the National Parents of Murdered Children organizations have long histories and expertise in dealing with victims of crime. As national organizations affirming the rights of victims, we strongly urge you to reconsider your recent decision to apply new lower penalties for crack cocaine offenses retroactively.

That decision you have made poses a severe risk to public safety for several reasons:

- According to your own estimates, approximately 20,000 offenders could have their sentences reduced. The sheer number of eligible offenders indicates the extent of the public safety risk.
- Many of these offenders will be released into vulnerable communities, which will risk further harm to the law-abiding citizens of these communities, who may not have the option of moving elsewhere. As Congress determines whether to address the Sentencing Commission's retroactivity decision, it must not forget the impact of that decision on these law-abiding citizens.
- Approximately two-thirds of these offenders have a serious criminal record that, according to your own studies, correlates to recidivism rates of between 34 and 55 percent. These high recidivism rates underscore the risk to these vulnerable communities.
- Many of these offenders may be unable to participate in Bureau of Prisons pre-release programs, such as halfway houses, due to the abrupt reduction in their sentences. Thus, they will be ill-prepared to return to their communities and their risk of recidivism increases.
- According to your own estimates, approximately 35% of these 20,000 offenders received an enhancement in their sentence for possessing a weapon or were convicted of a drug-related weapons offense. This highlights the risk of violent crime these offenders pose if released early.
- In conducting resentencing proceedings using the new lower guidelines, courts may not have complete information about the crime as much of that evidence will be stale and prosecutors will have difficulty presenting the pertinent facts. This will likely prevent judges from sentencing offenders appropriately based on the true extent of their criminal conduct.

We are concerned that the focus in this discussion is not on the victims and communities devastated by crack cocaine, but rather on crack cocaine offenders. Not only is it important to consider the rights and needs of the past and present victims of these offenders, it is crucial that

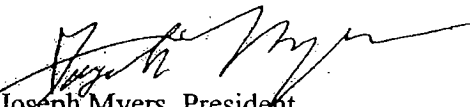
Kind regards,



Dan Levey, President
National Parents of Murdered Children



Nancy Ruhe, Executive Director
National Parents of Murdered Children



Joseph Myers, President
The National Organization for Victim Assistance



H. William Marling
Interim Executive Director