
William McConagha

Assistant Commissioner for Accountability and Integrity

U.S. Food & Drug Administration

Sentencing of Food and Drug Offenses

Before the

United States Sentencing Commission

February 13, 2008

Introduction

Members of the Commission –

Good morning. My name is William McConagha, and I am the Assistant Commissioner for Accountability and Integrity, U.S. Food & Drug Administration. I assumed this title in December 2007. Before becoming an Assistant Commissioner, I worked for thirteen years at FDA's Office of Chief Counsel (OCC).

During my tenure at OCC, I initially handled litigation matters with an emphasis on cases related to drugs and devices. By 1998, my practice focused almost exclusively on criminal enforcement actions. In September 2000, I began counseling FDA's Center for Drug Evaluation and Research on a variety of issues, including enforcement policy and actions related to human growth hormone. My areas of expertise include prescription drug importation, pharmacy issues, and the Prescription Drug Marketing Act (PDMA). I also sit on the agency's Counterfeit Drug Task Force. Before joining FDA, I litigated criminal cases for two years with the Office of the Public Defender for the State of Maryland.

As the Commission is aware, FDA is charged with the responsibility for investigating criminal violations of the Federal Food, Drug, and Cosmetic Act (FDCA), as amended by the Prescription Drug Marketing Act (PDMA), and other federal statutes related to the protection of the public health and safety. As a part of that responsibility, FDA appreciates this opportunity to address the need to establish a guideline for human growth hormone (hGH) offenses and the adequacy of the existing sentencing guidelines in addressing violations of the PDMA and the FDCA. As I will discuss, we at FDA believe that establishing an appropriate penalty framework for violations of the PDMA and other FDCA offenses is critical to provide a specific and general deterrent to crimes that threaten the nation's drug supply and the public health. For that reason,

we believe that realistic sentencing guidelines for these offenses is of vital importance to the agency's public health mission.

Human Growth Hormone Offenses Under 21 U.S.C. 333(e).

FDA is charged with criminal enforcement of illicit human growth hormone distribution in violation of 21 U.S.C. 333(e), and the lack of a sentencing guideline for these hGH offenses makes FDA's enforcement of this statute extremely difficult. In the absence of any guideline governing hGH offenses, prosecutors, defense counsel, and courts can 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), and 2X5.1 (which asks courts to make use of the criteria in 18 U.S.C. 3553 when no sufficiently analogous guideline is available). Because there is now substantial interpretive room at present in selecting an analogous guideline (as courts are directed to do by 1B1.2(a) when no specific guideline is available), the approaches and resulting sentences vary widely. The application of these varied approaches to sentencing hGH offenses has resulted in sentencing uncertainty, diminished deterrence, and perceived unfairness to defendants. As a result of the uncertainty surrounding how these offenses will be sentenced on conviction or guilty plea, it is more difficult for prosecutors to pursue those section 333(e) violations discovered by FDA/OCI investigations because the result of conviction is uncertain. When prosecution does take place, 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 you know, uncertainty

also diminishes deterrence when the criminal-minded underestimate the consequences of their conduct. The same uncertainty exists for the probation officers and judges charged with calculating and applying sentencing criteria. Even those courts that decide to compare hGH to a scheduled substance under 2D1.1, still face the difficulty of determining what quantity of hGH is equivalent to a "unit" for the purposes of Table C. Taken together, the uncertainties surrounding hGH sentencing have hampered FDA's ability to pursue enforcement of these violations and to prevent illicit hGH distribution.

The illicit use of hGH is a significant and growing problem that poses a variety of health risks to those who abuse hGH, including carpal tunnel syndrome, edema, high blood pressure, and diabetes. The incidence of these side effects prompts hGH users to self-administer with other dangerous drugs that can often dramatically increase the risk of adverse health consequences. These and other risks of hGH use will be discussed in greater detail by Dr. Robert Perlstein and Special Agent Alex Davis from FDA's Office of Criminal Investigations, but these risks underlay FDA's concern for the growing problem of illicit hGH distribution. That concern is heightened by the common misperception that hGH can be safely used as an alternative to steroids.

FDA's Proposal

FDA believes, in line with the Commission's recent proposal, that amending 2D1.1 to address violations of 21 U.S.C. 333(e) would substantially reduce the uncertainty that currently exists. Specifically, FDA recommends that the Commission use the total weight of hGH powder as the unit of measurement. As you are no doubt aware, calculation of quantity based on total weight of the substance is the approach used for most substances in Table C of 2D1.1.

In virtually all cases investigated to date by FDA, the illicit hGH products were

distributed in the form of a freeze-dried (lyophilized) powder that is intended to be mixed with a liquid such as saline for injection by the end user. This powder typically contains the hGH molecules and several excipient materials, such as mannitol, glycine, and phosphate. These excipient materials 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. Data gathered by FDA's Forensic Chemistry Center (FCC) from over two-hundred seventy five criminal investigations show that the active hGH ingredient makes up 6.4% of the total weight of the illicit product on average.

At present, in order to determine whether hGH is present in a particular sample and thus to confirm whether 21 U.S.C. 333(e) has been violated, 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 cuts 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, this additional burden 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 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 may 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 assessment 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.

Finally, with respect to hGH, the Commission has requested comment regarding what quantity of human growth hormone should be equated to a "unit" for the purposes of sentencing calculations under Table C of 2D1.1. To accomplish our shared goals of deterrence and fairness, FDA recommends that ten milligrams (10 mg) of total weight of powder containing hGH be equated to one "unit" for guidelines purposes.

Special Agent Davis will discuss in more detail the types of distribution schemes that FDA/OCI has encountered in its investigations. The quantities of hGH distributed in schemes investigated by FDA/OCI range from twenty 45-milligram vials of hGH to slightly over one thousand 45-milligram vials.[1] A cross-section of OCI cases in the last three years reveals that over 90% 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. With a substance as potent as hGH, not only does the culpability differ dramatically between a distributor who sells one gram (1,000 milligrams) and distributor who sells 9 grams (9,000 milligrams), but the public health implications also differ dramatically. Yet, based on the quantities of hGH seen in current FDA

[1] The data gathered by FCC indicate that vials of illicitly distributed hGH contain roughly forty-five (45) milligrams of powder containing hGH, on average.

cases, the individuals in both of these situations would receive the same base offense level of 6 if the conversion rate were set at 45-milligrams of total powder or at one "vial" per "unit" for sentencing purposes. Given the quantities of hGH actually being distributed and prosecuted, equating a large quantity of hGH, such as one vial or 45 milligrams of hGH, to one “unit” would result little or no stratification among offenders based on the quantity of hGH they are illegally distributing. FDA believes this result would not adequately deter mid-level and high-level hGH distributions. Without a meaningful distribution of offenders based on the quantity of hGH they distribute, access to Table C under 2D1.1 would not accomplish deterrence goals or fairly punish offenders based on relative culpability. This result is also inconsistent 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. 21 U.S.C. 333(e). We therefore recommend an equivalence of ten milligrams (10 mg) of hGH powder in order to more effectively stratify high-level, mid-level, and low-level hGH distributors and thus more effectively deter illicit conduct by matching sentencing to the quantity of hGH being illicitly distributed by an individual defendant. This approach would be consistent with Congressional intent, significantly improve FDA’s ability to obtain prosecutions of hGH offenders, and would be more fair to defendants.

The Prescription Drug Marketing Act

Congress enacted the Prescription Drug Marketing Act 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 seeks to establish a "closed system" for prescription drug distribution to prevent drugs from moving through illicit channels into the drug supply. The 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. The PDMA is primarily aimed at preventing prescription drug diversion, which threatens the integrity of the nation's drug supply. When it enacted the PDMA, Congress found that the mere existence of the wholesale drug diversion market "prevents effective control over or even routine knowledge of the true sources of prescription drugs in a significant number of cases." Id. 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.

Prescription drug diverters often operate outside of the legitimate distribution system and deal in discounted drugs obtained from questionable sources. These drugs may be stolen, unapproved, expired, counterfeit, or otherwise substandard. Illicit prescription drug diverters are concerned with profit rather than safety and lack the training, means, and motivation to store and handle prescription drugs properly. The mishandling and improper storage can adversely affect the drugs' potency, stability, and effectiveness. Illicit diverters often repackage and relabel drugs, sometimes under filthy conditions, to conceal the illegitimate source of the drugs. In their efforts to conceal the source of the drugs, the original expiration date and lot number are lost, impeding the ability to conduct effective recalls. In some cases, the offenders mix up drugs during the repackaging process, resulting in drugs labeled with the wrong drug name or dosage.

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.

Why are the existing guidelines inadequate? In many cases, offenders knowingly violate the PDMA without committing demonstrable fraud, and the cross-reference to 2B1.1, therefore, does not apply. The most frequent example occurs in cases involving unlicensed wholesale distribution of prescription drugs. 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 because the defendant did not misrepresent his licensing status or the source of the drugs to the purchaser and there is no evidence that the wholesaler took 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 serious public health risk.

Even when PDMA offenses involve fraud and the cross-reference to 2B1.1 applies, the calculation of "loss" under 2B1.1 is problematic. Under 2B1.1, "loss" means "pecuniary harm that resulted from the offense." U.S.S.G. 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, it is unclear under the current guidelines 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. While many diverted drugs may be subpotent or otherwise contaminated as a result of the conditions in which they are manufactured, stored, or repackaged, proving that a particular drug is substandard may be difficult. For example, the cost of testing may be prohibitive, no reliable method of testing may exist to determine whether a particular drug is adulterated (e.g., whether an expired drug was potent enough at the time it was seized to be effective), or the drugs themselves may be unavailable for testing because they may already have been distributed. As discussed earlier in the context of the uncertainty surrounding hGH sentencing, this lack of clarity diminishes deterrence, creates a similar difficulty for prosecutors when considering whether to pursue PDMA violations, thus hindering FDA's ability to protect the nation's prescription drug supply, and encourages an unwarranted disparity among offenders convicted of similar criminal conduct.

Recommendations

The problem with the existing guidelines could be solved by amending 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 Section 2B1.1 to clarify the appropriate calculation of loss. Specifically, the Commission might 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 all of 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.

An alternative 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. In that event, 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), in lieu of the cross-reference to 2B1.1. Proposed amendment language along these lines is attached to this statement as Attachment A. 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 places the safety and effectiveness of prescription drugs at risk. 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 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 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 distributed by an illicit source in knowing 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 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.

In conclusion, with respect to PDMA offenses, we believe that either of these suggested amendments would more accurately reflect Congressional intent, 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.

Other FDCA Offenses

FDA also believes that the current guidelines under 2N2.1 are inadequate to address the significant public health consequences of a wide variety of FDCA offenses. For example, the FDCA in Title 21, Section 331, includes more than twenty four (24) prohibited acts, each of which encompass a large range of conduct. For example, one portion of Section 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. We recognize the magnitude and complexity of reforming this section in order to sentence such a broad range of conduct more appropriately, and we acknowledge that a comprehensive solution to the problems posed by the inadequacy of 2N2.1 to sentence all FDCA offenses is beyond the scope of today's hearing. However, we would like identify one significant problems and offer a preliminary suggestion to address it.

Adulterated or Misbranded Drugs and "Loss" Calculations

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. 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 purported 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.[2] This 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. We believe that including an application note that clarifies how courts should calculate loss for offenses involving misbranded or adulterated FDA-regulated products would promote consistent application of the guidelines and would deter the sale of these illegal and often dangerous products.

Conclusion

We appreciate the Commission's consideration of these issues and look forward to assisting the Commission's efforts in whatever way possible.

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

William McConagha

Assistant Commissioner for Accountability and Integrity

U.S. Food & Drug Administration

Attachment A

Possible Amendment of 2N2.1 For PDMA Violations

2N2.1 Violations of Statutes and Regulations Dealing With Any Food, Drug, Biological Product, Device, Cosmetic, or Agricultural Product

(a) Base Offense Level (Apply the greater):

(1) 6

(2) 12, if the offense involved a violation subject to 21 U.S.C. 333(b)(1).

(b) Cross References

(1) If the offense involved fraud, apply § 2B1.1 (Theft, Property Destruction, and Fraud), except for violations subject to 21 U.S.C. 333(b)(1).

(2) If the offense was committed in furtherance of, or to conceal, an offense covered by another offense guideline, apply that other offense guideline if the resulting offense level is greater than that determined above.

(c) Specific Offense Characteristics For Offenses Under 21 U.S.C. 333(b)(1)

(1) If the offense involved failure to adequately store or handle prescription drugs, increase by 4 levels.

(2) If a drug involved in the offense was unapproved (including foreign manufactured versions of an FDA approved drug), previously dispensed, expired, or counterfeit, increase by 4 levels.

(3) If the defendant failed to establish and maintain records of the receipt and distribution of prescription drugs, increase by 2 levels.

(4) If the offense involved the distribution of prescription drugs with an average retail value greater $50,000, increase the offense level as follows:

Average Retail Prescription Drug Value		*Increase In Level*
(A)	*$50,000 or less*	*no increase*
(B)	*More than $50,000*	*add 2*
(C)	*More than $250,000*	*add 4*
(D)	*More than $500,000*	*add 6*
(E)	*More than $1,000,000*	*add 8*