PREPARED REMARKS

OF

HYMAN, PHELPS & MCNAMARA P.C.

BEFORE THE

UNITED STATES SENTENCING COMMISSION

PUBLIC BRIEFING CONCERNING

PDMA OFFENSES

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PRESENTED BY:

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Good morning Commissioners, Commission staff, and panel colleagues. My name is John Gilbert, and I am a Director at the law firm Hyman, Phelps & McNamara, P.C.[1] I appreciate the opportunity to share our firm's views on the Commission's proposed amendments to the Sentencing Guidelines. I will be presenting comments specifically on the proposed changes and issues identified by the Commission to the 2N2.1 Guideline with respect to the Prescription Drug Marketing Act or "PMDA" violations, the penalties for which are set forth in 21 U.S.C. § 333(b).

In the published Federal Register notice, the Commission posed the following issue related to the PDMA:

> **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?**

It appears that these questions were prompted by comments from the Food and Drug Administration, which wrote the Commission stating that:

> **§ 2N2.1 does not adequately punish violations of the PDMA, which carry a 10 year statutory maximum term of imprisonment.**

[1] The views expressed in these Remarks and any oral Remarks given today by Mr. Gilbert should not be considered as the views of any of this firm's clients.

In order to properly address the question of whether the current sentencing guidelines, § 2N2.1, adequately punishes PDMA offenses, it's first important to understand the purpose and scope of the PDMA. The PDMA was enacted in 1987, as amending the FDC Act. Like the broader FDC Act, the PDMA is first and foremost a regulatory statute that imposes certain requirements and restrictions on the distribution and marketing of prescription drugs.

From the beginning, there has been some ambivalence about the PDMA given concerns about whether the law was necessary to address the perceived problems with marketing prescription drugs and the potential imposition of anticompetitive requirements. There was also concern that the law imposed certain federal requirements on states, e.g., wholesale distributor licensing.

The law addresses four primary areas: (1) it bans reimportation of American-made prescription human drugs from foreign countries except by the manufacturer or in emergencies; (2) it regulates the distribution of prescription "drug samples"; (3) it prohibits, with certain exceptions, the resale of prescription drugs purchased by hospitals, health care entities and

charitable institutions; and (4) it regulates prescription drug wholesale distributors.

The PDMA covers a number of regulatory areas; therefore, it is not very helpful in analyzing the penalty provisions to speak of the PDMA offenses monolithically. That said, the most frequently charged violation since the PDMA has been enacted involves the unlawful purchase or sale of prescription drug samples.

From the outset, the PDMA has imposed a ten year statutory maximum for criminal violations. Interestingly, the original PDMA, like the rest of the FDA Act did not contain a knowledge requirement. So it was similar in context to other FDA misdemeanor offenses. However, unlike other FDA misdemeanor offenses, the PDMA has always included a much tougher ten year statutory maximum, not a one year statutory maximum. In the 1992 amendments to the PDMA, the scienter requirement was clarified to ensure that only "knowing" violations are subject to the criminal penalties.

Because the PDMA is predominantly a regulatory statute imposing restrictions on the legitimate industry, prosecutors can find it difficult if not confusing to pursue criminal penalties under the statute. More often, prosecutors will rely on a more straightforward criminal statute, like mail or

wire fraud for prosecuting crimes that have an intent or fraud element. Thus, it is not uncommon to see conduct violative of the PDMA charged under those statutes. Alternatively, there are cases where a prosecutor will charge a defendant with adulteration and misbranding under the FDC Act and not PDMA, involving samples that have been repackaged, or samples relabeled for resale. This provides an effective avenue for prosecutors to utilize the FDC Act felony charges alleging that the conduct was done with the intent to defraud and mislead. In short, many cases involving violations of the PDMA are charged and sentenced under the fraud guideline.

For example, in U.S. v. Tobin, 1995 U.S. Dist. LEXIS 9651 (N.D. Ill. 1995) the defendant pled to PDMA violations for the purchase of drug samples and was sentenced to a term of 8-14 months imprisonment under the fraud guideline. Thus, the existing fraud guidelines proved more than adequate to criminally prosecute such behavior. There are several other examples where the fraud guidelines have proven effective for prosecuting PDMA violations where fraud is an element of the crime. See e.g., Virgil Lee (W.D. Wis. 1993) (14 months in jail; $95,000 restitution; $5,000 fine). More recently, in U.S. v. Millstein, 481 F.3d 132 (2d. Cir. 2007), the court affirmed a 20 month sentence in a case involving PDMA violations.

One of the most well-known criminal prosecutions involving violations of the PDMA is the TAP case which was settled in 2001. U.S. v. Tap Pharmaceutical Products, Inc., 1:01-cr-10354-WGY (D. Mass.) (judgment entered Dec. 10, 2001). This case involved allegations that company sales representatives provided drug samples to practitioners knowing that doctors would seek payment or reimbursement for the drug samples. TAP pled to one count of conspiring with physicians to violate the PDMA (by selling Lupron samples), paid a $290 million criminal fine and also agreed to a civil settlement under the False Claims Act and the Medicaid Rebate statute. In addition, six TAP employees, district managers and other sales management were charged with payment of kickbacks, conspiracy with physicians to violate the antikickback law and PDMA violations ("selling" samples). Thus, in addition to the PDMA, this case involved aiding and abetting the sale of samples (18 U.S.C. §2); conspiring to cause the sale of samples (18 U.S.C. §371); conspiracy to defraud the government (18 U.S.C. § 371); payment of illegal remuneration, 42 U.S.C. § 1320a-7b(b) and violations of the False Claims Act 31 U.S.C. § 3729.

At the time of the settlement, the TAP case was the largest criminal and civil recovery in a health care fraud case, so it's difficult to accept a general statement that a prosecutor can't get adequate sentences for PDMA

offenses. TAP isn't the only large criminal penalty in a PDMA case. In 2003, AstraZeneca paid a $64 million criminal fine for PDMA violations concerning the unauthorized selling of samples for the drug Zoladex.

TAP and AstraZeneca were "big" cases and not all PDMA cases are big cases, but when the statute is implicated in an investigation and prosecution, the evidence that I am aware of suggests that the current Guidelines work. It also indicates that where criminal conduct rises to a level of fraud, there are adequate provisions to criminally prosecute such behavior.

There are other examples that illustrate this point. FDA's Enforcement Story for FY 2000 contains sentencing information for two different investigations involving PDMA cases. The first group of cases in New Jersey involved resale of samples, and the defendants were sentenced to sentences ranging from six months of incarceration and 60 months probation (Paul Nuzzolo) to 12 months probation (Nick Pirovolos). In the second group of cases involving unlicensed wholesale distribution of Viagra, four defendants were sentenced to six month jail terms.

Even within a given investigation, a review of the caselaw demonstrates that the courts have imposed a fair and adequate range of sentences. In its FY 2005 report, FDA reports on several convictions arising

out of a scheme to distribute samples, and reports that one defendant was sentenced to a year and a day, and the others received sentences of home detention and probation.

The above discussion of cases certainly isn't exhaustive but it demonstrates that PDMA violations are prosecuted, and defendants routinely go to jail for those violations. Whether they go to jail for as long as FDA might like, or whether the lack of sufficient sentences are the result of defects with the Guidelines, or other issues, would require a more in-depth analysis. But our point is that this is not the kind of record before the Commission that currently warrants an amendment to the Guidelines for PMDA offenses.

I'd echo the comments presented by my colleague John Fleder that there is no evidence that the system is broken. I'd further reiterate the suggestion he put forward that if the Commission is inclined to do anything, it should make a referral to a working group like the Food and Drug Working Group to study the actual record of PDMA prosecutions and sentences so that the Commission can make an informed decision.

Given the breadth of the PDMA in regulating the scope of marketing and distribution of legitimate prescription drugs, we have serious reservations about the wisdom of assigning a higher base offense level for

PDMA offenses as FDA has suggested. There are new challenges facing the legitimate industry in the marketing and distribution of prescription drugs such as changes in federal and state drug pedigree requirements. Many PDMA violations–just like the general FDC Act violations–are truly regulatory in nature, and to say that these violations should start at a base offense level of 12 or 14 creates an unwarranted prosecutorial environment, given our experience with regard to the general compliance history of the regulated industry. For example, this action would place an unduly large amount of power in the hands of a prosecutor who wants to get cooperation from company executives who may not think they or their company has done anything wrong.

The Guidelines already provide significant bases for adjustments and departures, so if the government and a court believe that a case needs to be sentenced at the statutory maximum of the PDMA to achieve sentencing goals, 2N2.1 is not going to stand in their way.

With respect to the concern that the change is needed for its deterrent effect, the TAP and AstraZeneca cases are instructive. These cases indicate that there are sufficient penalties available. There was also a civil component and an administrative component, which is true in most of these

cases. Thus, the deterrent effect in a PDMA case does not derive solely from the Guidelines.

In sum, there is not sufficient evidence for the case that the Guidelines need to be revised with respect to PDMA. If there is an as yet unspecified need for a revision to the Guidelines, the Commission should be presented with empirical evidence that provides a basis for the Commission to make a decision on a well-developed analysis of the record. That does not appear to be the case at this time and we recommend that the Commission not move forward with a revision at this juncture.

I'd be happy to answer any questions.