PREPARED REMARKS

OF

HYMAN, PHELPS & MCNAMARA P.C.

BEFORE THE

UNITED STATES SENTENCING COMMISSION

PUBLIC BRIEFING CONCERNING

FEDERAL FOOD, DRUG, AND COSMETIC ACT OFFENSES

FEBRUARY 13, 2008

PRESENTED BY:

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Good morning Commissioners, Commission staff, and panel colleagues. My name is John R. Fleder, and I am a Director at the law firm of Hyman, Phelps & McNamara, P.C.,[1] a firm that specializes in representing clients that are closely regulated by the United States Food and Drug Administration (FDA) under the Federal Food, Drug, and Cosmetic Act (FDC Act). I am honored to be here today, and appreciate the opportunity to share the views of my colleagues and me regarding possible amendments and issues for comment that the Commission recently published regarding the 2N2.1 Guideline.

The first time that I was involved in responding to a Commission proposal regarding 2N2.1 was twelve years ago. That proposal was based upon the suggestion to eliminate the 2N2.1 guideline entirely and to have courts sentence all FDC Act cases under the harsher fraud guideline. Based at least in part upon the industry's strong negative response, that proposal was withdrawn.

So here we are twelve years later, considering different changes to 2N2.1 based on FDA's suggestion that the Commission should consider wholesale revisions to the 2N2.1 Guideline. The Commission has proposed that the commentary to 2N.2.1 be amended to include substantial risk of bodily harm or death as a basis for an upward departure. In addition, the Commission seeks comments on whether it should provide alternative base offense levels and specific offense characteristics that would identify aggravating factors warranting an enhanced sentence.

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

My view remains the same as it was years ago, which is that there is no evidence that the system is broken or that the proposed changes to 2N2.1 (with the exception of the Commission's "second offense" proposal) are necessary or appropriate based upon the FDC Act statutory scheme, the purposes of the Guidelines, or the actual record of FDC Act criminal enforcement. So if the Commission is inclined to do anything else, we suggest that the Commission refer these issues to a Food and Drug Working Group, like the working group convened in 1994. In sum, the publicly available letters from FDA to the Commission simply do not justify significant changes to a Guidelines system that is working appropriately for FDC Act misdemeanor offenses.

That being said, the proposal to add a specific offense characteristic to add a 2-7 level increase when a defendant is convicted of a second FDC Act violation makes sense. The statute makes a second FDC Act offense a felony regardless of intent, and the proposed addition of 2-7 levels provides sufficient flexibility that, even with the increase, appropriate sentences could result.

We would like to add one technical point on that language. We note that the second offense provision (21 U.S.C. § 333(a)(2)) applies only after a conviction "has become final." In contrast, the proposed Guideline change would apply if the defendant "committed any part of the instant offense after sustaining a conviction." It is not clear that a "final conviction" is the same as a "sustained conviction" and it may be cleaner to just track the statutory language in a final change to the Guideline.

Let us offer a discussion of the bases for our conclusion that further changes to 2N2.1 are not warranted. Prior to entering private practice, I spent over nineteen years as a prosecutor for the Department of Justice, enforcing the FDC Act. In my last seven years as a prosecutor, I was the Director of the Office of Consumer Litigation (OCL), the Office that by DOJ regulations, is responsible for all civil and criminal matters under the FDC Act.

In preparing to testify today, I have discussed the Commission's proposed amendments with my colleagues at Hyman, Phelps & McNamara P.C. including: (1) Douglas B. Farquhar, who spent seven years as a prosecutor in the District of Maryland and handled numerous FDC Act cases for the government, and has similarly handled numerous FDC Act cases for clients in his time in private practice; and (2) J.P. Ellison, who just recently joined our firm from OCL. I am also especially pleased today to be here with my colleague and fellow Director, John A. Gilbert, a former DEA attorney, who has particular expertise with the Prescription Drug Marketing Act and controlled substances, but who also has a broad range of experience with FDC Act cases. Thus, our comments reflect a wide range of experiences with FDC Act cases from both a government and defendant perspective.

At the outset, it is important to recognize what we are ***NOT*** talking about today, namely fraud cases involving FDC Act-regulated products. As the Commission knows, under the 2N2.1 guideline, if the offense involves fraud, the 2B1.1 guideline applies. 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". This has been true for approximately 20-25 years. In contrast, when I first started as a prosecutor in the 1970's, most FDC Act cases were misdemeanor cases. That means that the amendments to 2N2.1 will not impact most of the FDC Act cases brought in this era, and will not relate to those persons who intentionally flaunt the public health and safety by engaging in fraudulent conduct.

Second, it is critical to emphasize that the misdemeanor cases that would be impacted by the Commission's proposal are strict liability regulatory offenses. The Supreme Court has established a very low bar for the Government to meet in terms of the burdens placed on the Government to prove one of these cases. The case most frequently cited in connection with the strict liability nature of these FDC Act cases is the "Park" case, United States v. Park, 421 U.S. 658 (1975).

In Park, the Court upheld the misdemeanor conviction of Mr. Park under the FDC Act based on the premise that people who manage FDC Act-regulated businesses (in Mr. Park's case it was a food business, but this doctrine also applies to the drug and medical device industry) have an affirmative duty to insure that the products that they sell are safe. As a result, persons can be prosecuted even if an individual does not even know that a violation of law is occurring.

Now, as a consumer, and as a matter of administrative and perhaps even civil law, this notion makes a lot of sense. For purposes of criminal law the so-called "Park doctrine" puts a huge amount of power in the hands

of a prosecutor, because under Park, it means that for an FDC Act violation committed by a company, all of its corporate officers and others could be deemed to be in a "responsible relationship" to some illegal activity by the company, and can thus be charged with a criminal misdemeanor, even though no officer personally engaged in, or even knew about, the illegal activity.

To better understand what that means in practice, we would like to briefly mention the facts of the Park case. Acme Markets, Inc. was a national retail food chain with approximately 36,000 employees, 874 retail outlets, and 16 warehouses. Its headquarters, including those of its president John Park (the defendant), were in Philadelphia, Pennsylvania. Mr. Park and Acme Markets were charged in Baltimore, Maryland with misdemeanor sanctions under the FDC Act. The government alleged that they received foods that had been shipped in interstate commerce, and while the food was being held in the Baltimore warehouse, the food became accessible to rodents. Acme pleaded guilty, but Mr. Park went to trial and was convicted on all five counts he was charged with.

Before the charges were filed, FDA had advised Mr. Park of insanitary conditions in the Philadelphia warehouse. In 1971, FDA found similar conditions at the Baltimore facility and so informed Mr. Park. After Mr. Park got this information, he consulted with Acme legal counsel who told him that the person in charge of the Baltimore facility was investigating the situation. A second violative–but improved–inspection of the Baltimore facility occurred in March 1972. Mr. Park later testified that there was nothing further for him to do.

The Supreme Court noted that criminal penalties under the Food and Drug laws, dating back to 1906, had been applied to persons by virtue of their managerial positions. It was enough that, by virtue of the relationship the defendant bore to the corporation, he had the power to prevent the act complained of. The Court stated that the FDC Act punishes neglect where the law requires care or inaction where it imposes a duty. The Court said that the Act 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.

The upshot of this doctrine is that an individual can be convicted of a federal crime of violating the FDC Act, based solely upon his or her position within an organization.

We would also like to mention a model jury instruction from the "Resource Manual" of the United States Attorney's Manual[2] (USAM), on charging FDC Act misdemeanors. This instruction demonstrates the Government's view as to the almost limitless potential liability imposed on individuals under the misdemeanor provision of the FDC Act:

> CORPORATE OFFICIAL'S LIABILITY FOR VIOLATIONS OF FEDERAL FOOD, DRUG, AND COSMETIC ACT
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> In order to find the defendant guilty, you do not have to find that he personally committed acts causing food to become adulterated. You may find that the defendant caused the

[2] 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.

adulteration of food if you find beyond a reasonable doubt that, by reason of his job, the defendant had the responsibility and authority to prevent adulteration from occurring, or to promptly correct any adulteration, and that he failed to do so.

Moreover, it is no defense to the crimes charged in the Information that the defendant did not intend adulteration to occur, or that he lacked knowledge of the specific circumstances that caused adulteration. The law does not require the defendant to have actively engaged in wrongdoing in order to be held responsible for the adulteration of food being held for sale in his processing plant. All that the law requires is that the defendant held such a position of responsibility within the enterprise that he had sufficient authority to prevent or correct the dangerous conditions and thereby prevent the adulteration of the food. Responsible agents of businesses whose services and products affect the public health have a legal duty to exercise the foresight and vigilance necessary to ensure that their products are not adulterated and are therefore safe for public consumption. The Federal Food, Drug, and Cosmetic Act imposes this duty because responsible agents have at least the opportunity to learn of, correct, or prevent insanitary conditions, whereas even the most cautious consumer is unable to protect himself.

So under the FDC Act, the CEO or President and indeed many other company officials of every FDA-regulated company could face a criminal charge every time there is an FDA violation. Publicly-available FDA documents show that many, if not most, companies inspected by FDA have at least one violation of the FDC Act. This violation, with or without prior warning by FDA, subjects "responsible" individuals to the harsh possibility of a criminal prosecution. Thus, it is up to the prosecutorial discretion of FDA and DOJ whether such criminal charges are brought.

Significantly, the USAM Resource Manual recommends that when felony charges are commenced "the prosecutor may want to request that the jury be instructed on the lesser-included misdemeanor offense." So what this means is that the government goes for a felony conviction and loses, it can still obtain a misdemeanor conviction where the finder of fact says that there was no intent to defraud or mislead. Well, unless the government was unable to prove up the underlying regulatory offense, for example, that the product was "adulterated" or "misbranded" – (which, by the way, are terms of art under the FDC Act and do not necessarily mean that anything was wrong with the product from a health and safety perspective) – the government can still get a misdemeanor conviction under Park.

You can imagine that a prosecutor who has just tried and lost a felony FDC Act case which he or she spent time developing and pursuing, might be aggressive in seeking penalties in the sentencing phase if he or she was able to get that underlying misdemeanor conviction despite losing on the felony charges. And fortunately or unfortunately, you do not have to imagine it because there was a recent case in which that very thing happened. For

short-hand, I'll call the case the Kaminski case, which was the name of the 6th Circuit appeal. The cite to the case is 501 F.3d 655 (6th Cir. 2007). The district court decision is reported at 370 F. Supp.2d 661 (S.D. Ohio 2005).

Kaminski involved a twenty-three count felony criminal indictment against Mitchell Kaminski, Marilyn Coleman, and Ovimmune, Inc. (a company that they ran together). They were charged with running a criminal conspiracy, engaging in mail fraud, and felony violations of the FDC Act, all arising out of the defendants' sale of about $83,000 worth of so called "hyperimunne eggs" laid by chickens who had been vaccinated. It seems that Ms. Coleman and her company thought these eggs were foods, and the egg powder a dietary supplement. FDA disagreed, however, and made a federal criminal case out of it. The jury rejected all the allegations of fraud, acquitting the defendants on the conspiracy and mail fraud counts. However, the jury convicted the defendants of five unapproved new drug counts, seven misbranded drug counts, one count of failure to register a drug manufacturing facility, and two adulterated drug counts. Again, the jury rejected any fraud allegations, and thus convicted the defendants only of misdemeanors. The government sought to impose a sentence of 30-37 months based upon these convictions.

It is important to keep in mind that the FDC Act is not the easiest statute to interpret. In a case from late 2006, in trying to parse a different section of the FDC Act, Judge Titus in the District of Maryland commented that "There's a special place in Hell where they torture people who write

things like this."[3] Indeed, it is not uncommon for prosecutors to decline FDA criminal cases because the complicated regulatory nature of the offense will be difficult to explain to a jury. Put another way, difficulty in proving a violation of the FDC Act, not the sentence to be imposed, is often the reason that prosecutors have declined to commence criminal cases investigated by FDA.

Our firm spends a lot of time helping companies and individuals sort out very difficult issues concerning whether a product is a food, a drug, a device, a cosmetic, etc., and regardless of the classification of the product, whether a company's actions are or are not in compliance with the complex regulatory requirements of the FDC Act. Nevertheless, many companies and persons do not undertake to violate the FDC Act, with fraudulent intent or even any wrongful intent. Yet, they may simply not comprehend the complicated legal system enforced by FDA. On a personal note this complicated statutory scheme keeps our firm and other food and drug law firms in business.

And so the first question is, what is wrong with starting with a base offense level of 6 in these sorts of cases? The next question is does the Sentencing Commission truly need to provide Specific Offense Characteristics?

As the Commission well 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 fashion a sentence appropriate to

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[3] Biovail Corp v. FDA, 8:06-cv-03355-RWT (D. Md.) (transcript of hearing held on December 21, 2006).

the particular facts and circumstances. Indeed, these Adjustments were relied upon by the Government in the Kaminski case when it sought the sentence discussed above. The district court's decision to sentence the defendants well below the sentences requested by the Government apparently had nothing to do with the court being hamstrung by inadequate Sentencing Guidelines. Instead, the court decided against a jail sentence after taking many factors into consideration, including that the individuals had been acquitted of the more serious felony charges.

It also merits mention how significant a criminal FDC Act charge (whether it is a misdemeanor or felony) is to a legitimate company and its employees. For these companies and their employees, the collateral consequences of being charged with a criminal violation of the FDC Act, let alone convicted, are huge. Whether you are a large and well-established company, or a small start-up trying to get a toe-hold in the market, a press report stating that you have been charged with a criminal violation of the FDC Act can have devastating effects. Thus, the notion that these companies and their employees are willing to risk a criminal conviction because the base offense level is a 6 rather than a 10, just does not have any basis in fact. Again, for a company that is not a legitimate company, whose purpose is to deceive FDA or consumers, their prosecution is not a 2N2.1 case. That case is going to be sentenced under the fraud guidelines.

If FDA perceives that it has a problem that it cannot get DOJ's attention to bring misdemeanor cases, the recent pet food indictments show that DOJ can and will bring FDC Act misdemeanor charges. Just last week, the United States Attorney for the Western District of Missouri commenced

an FDC Act misdemeanor case against certain persons, while reserving FDC Act felony charges for others.[4]

We are not unsympathetic to the notion that FDC Act misdemeanor cases are a lot of work that may not bring the sentencing "return" that the prosecutor envisioned when he or she started the case. I was a young prosecutor in the "heyday" of the FDC Act misdemeanor prosecutions in the 1970's and we often saw judges giving fines of $30-$50 for those convictions. In fact, in the Park case, Mr. Park was assessed a $50 fine for each of his 5 counts of conviction. But again, from what we have seen, the 2N2.1 Guideline, supplemented by the other existing Guidelines, does adequately provide judges with the necessary flexibility to impose a harsh sentence when warranted. Indeed, we are not aware of a single case (and FDA letters certainly do not cite one) where a Judge saw the existing 2N2.1 Guideline as a barrier to an appropriately harsh sentence.

Moreover, as a practical matter, the vast majority of these criminal FDC Act cases do not arise in a vacuum. There is frequently a civil component to the government's enforcement (often times under the False Claims Act), and the persons and entities being investigated by FDA are also worried about administrative remedies that regulatory agencies have at their disposal, including but not limited to exclusion and debarment. This explains why so many of these cases with FDC Act charges in them (whether they are felonies or misdemeanors) result in global resolutions of liability and involve so-called "(c) pleas" under Federal Rule of Criminal Procedure 11(c); the defendant is not just worried about the FDC Act charge,

[4] United States v. Sally Miller, No. 4:08-cr-00023-DW (W.D. Mo. Feb. 6, 2008).

he is also concerned about a variety of other government enforcement actions.

Most legitimate companies and their executives are not interested in going to war with FDA. They need long-term peace with the Agency, in order to survive in a closely regulated industry. If a prosecutor threatens criminal prosecution, few legitimate companies and individuals are willing to undergo the public scrutiny and criticism attached to an Indictment that is not accompanied by a global resolution. Often, finality is more important than vindication.

As a result, the prosecutor holds the key to the defendant's future. If the prosecutor and FDA believe that a serious sentence is warranted they will demand one in negotiations. At that point, the company official will usually have little leverage. As a result, the sentence sought by the prosecutor will depend heavily on his or her own instinct as to the sentence warranted by the conduct, and that assessment will often bear little or no relationship to the applicable Guideline. Put another way, while the 2N2.1 Guideline is obviously crucial when a case goes to trial and a conviction follows, it has little to no bearing on the vast majority of cases where a legitimate company official agrees to plead guilty.

Resolution of criminal cases by plea based upon such considerations is not unique to FDC Act misdemeanor cases, and in fact influences not only nearly all FDC Act criminal cases (felonies and misdemeanors), but also affects criminal cases in other regulated industries as well. What is different about FDC Act misdemeanors (and other strict liability criminal cases), is

the absence of an intent element. In the vast majority of criminal cases, the government has to at least consider litigation risk associated with proving intent to a jury, and thus may compromise on a resolution with a defendant. In an FDC Act misdemeanor case, the government does not worry about intent, so there is precious little to dissuade a prosecutor who wants to forge ahead with a misdemeanor prosecution. Congress has decided that is how FDC Act misdemeanors should operate, and we do not have a quarrel with that. However, we do not see any evidence that prosecutors need a harsher 2N2.1 Guideline for the system to work the way Congress intended.

In sum, the 2N2.1 system appears to us to be working just fine. Before the Commission takes any radical action to revise this Guideline, we urge you to have a much more fully developed factual and legal record than that which has been presented to date about the need for the proposed changes.

Thank you very much for giving me the opportunity to present our views.

I am happy to answer any questions.