

JEFFREY S. PARKER

**George Mason University
School of Law
3401 North Fairfax Drive
Arlington, Virginia 22201
(703) 993-8087
Fax: (703) 993-8088**

March 14, 1996

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

Attention: Public Information

RE: Comment on Proposed Guideline Amendments

To the Commissioners:

I am submitting this letter of comment in response to the Commission's Federal Register notice of January 2, 1996, 61 Fed. Reg. 79, with specific reference to the proposed Guideline amendments concerning food and drug offenses, id. at 83. I believe that these proposed amendments are unwise in the extreme, inconsistent with some of the central features of the federal Guidelines system as it has been known since its original promulgation in 1987, and potentially disruptive to the fair administration of criminal justice in the federal courts. Accordingly, I recommend that the proposed amendments be withdrawn pending further study by the Commission and its staff, which obviously has failed to consider some of the broad-ranging implications of this proposal.

My interest in this matter is two-fold. First, the amendments in question were brought to my attention quite recently by the Pharmaceutical Research and Manufacturers of America ("PhRMA"), which engaged me, as an expert in sentencing law and policy, to analyze and comment to you on the proposed amendment.¹ Second, I have a longstanding interest in the success of the Commission's work, having served as Deputy Chief Counsel (1987-88) and Consulting Counsel (1988-89) to the Commission, in both capacities primarily engaged in the development of sentencing guidelines for

¹Although I am to receive my ordinary hourly consulting fee for this work, no one associated with PhRMA has suggested the substance of my comments or reviewed or approved the contents of this letter. Therefore, I am not "representing" PhRMA in the usual use, and my comments do not necessarily represent the views of PhRMA or any of its members. I have no other affiliation with PhRMA, and have done no other work for them.

organizations and white-collar offenses, and, as an academic,² having published several papers on federal sentencing law and policy and substantive criminal law, with the same emphases.³

As a participant in and observer of the Commission's process for some years now, I am not unmindful of the complexities involved in developing and refining sentencing guidelines, which I believe has a subtlety unmatched by almost any other aspect of governmental policymaking, given the variety of different actors who are affected by sentencing guidelines in different ways--including prosecutors, judges, probation officers, defendants, and potential defendants--which includes all of us in some capacity. Furthermore, the Commission itself must walk a tightrope narrowly drawn by the Commission's unique position within the governmental structure and its delicate mandate to develop sentencing policy without encroaching upon legislative or substantive legal policy, surrounded by potential critics from the Executive, the Congress, the courts, the legal community, regulated industries, and the public at large. Accordingly, I am quite aware of how much easier it is to be an external critic than an internal guidelines-maker, and my critical comments should be taken in this light.

Notwithstanding my empathy for the Commission's difficult situation, I believe that the Commission is slipping off of its tightrope in this particular instance, and it should catch itself before it falls into the void. This proposed amendment not only is unjustified on its own narrow terms, but also is likely to have very profound consequences for all guidelines sentencing that the Commission does not appear even to perceive, much less to have considered adequately.

As I understand the Federal Register notice, the proposal is to withdraw the current food and drug offense guideline, §2N2.1, and henceforth to sentence all offenses formerly covered by that guideline under §2F1.1, as if they were all offenses involving fraud or deceit. The only amendment proposed to §2F1.1 to accommodate its new coverage would be a guided upward departure suggested by the application notes in cases where "a large number of persons" were affected by a risk of serious bodily injury. In addition, the notice proposes to add food and drug offenses to the organizational sentencing guidelines of current Chapter 8, which as promulgated in 1991 excluded those offenses from its coverage. Finally, the notice seeks comment on an entirely new concept of using gain rather than loss as a measure of offense severity "when the essence of the offense is fraud against regulatory authorities with no economic loss." This last point does not appear explicitly to

² Currently, I am Professor of Law and Associate Dean for Academic Affairs at the George Mason University School of Law. Of course, my comments here also do not represent the policy or views of George Mason University or the School of Law.

³ Jeffrey S. Parker, *Criminal Sentencing Policy for Organizations: The Unifying Approach of Optimal Penalties*, 26 Am. Crim. L. Rev. 513-604 (1989); Jeffrey S. Parker & Michael K. Block, *the Sentencing Commission, P.M. (Post-Mistretta): Sunshine or Sunset?*, 27 Am. Crim. L. Rev. 289-329 (1989); Jeffrey S. Parker, *Rules Without . . . : Some Critical Reflections on the Federal Corporate Sentencing Guidelines*, 71 Wash. U.L.Q. 397-442 (1993); Jeffrey S. Parker, *The Economics of Mens Rea*, 79 Va. L. Rev. 741-811 (1993).

be limited to food and drug offenses only.

The announced basis for the proposal is the February 1995 Final Report of the Commission Staff's Food and Drug Working Group (hereinafter the "Staff Report"). I recently have reviewed the Staff Report, and I must say that I am surprised to find it cited as the basis for the proposed amendment, as that Report does not recommend--nor even contemplate--the principal action now proposed by the Commission, which is to abolish §2N2.1 in its entirety. Rather, the Staff Report had raised the question of consistency in the application of a pre-existing cross-reference between §2N2.1 and §2F1.1. Even on its own terms, I believe that the Staff Report is based upon an unwarranted inference from the case files. But in any event, it focuses on a very different consideration from the radical measure now proposed in the Commission's notice.⁴

A. Abolition of § 2N2.1

Focusing first on the principal proposal to abolish §2N2.1, I see three major objections, all of which create serious problems of either substantive legal policy or consistent sentencing policy, or both, as that proposal would: (1) obliterate important culpability distinctions both within the underlying food and drug statutes and between those statutes and the very different statutes currently covered by the fraud guideline; (2) undermine a basic feature of the sentencing guidelines overall as being primarily a "charge offense" rather than a "real offense" sentencing system; and (3) deviate fundamentally from the guidelines' overall approach to regulatory offenses. These would all be profound changes to the federal sentencing guidelines' structure as it has existed since 1987, and yet none of them is even recognized as a consequence of the proposal in either the Staff Report or the Commission's notice.

1. Culpability Distinctions. There appears to be no recognition by the Staff Report that the principal statutes now covered by §2N2.1 do not require *any* proof of mens rea or criminal culpability in the usual sense for a conviction. In fact, they are the leading examples of "strict liability" criminal offenses. By the general standards of criminal law, they are not "crimes" at all;⁵ and they are often

⁴ Aside from the Staff Report, the only other background of which I am aware is a meeting that was held in February 1996 between Commission staff members and Messrs. John Fleder and James Fletcher, representing pharmaceutical and food industry groups, at which the staff is said to have indicated that the proposal was a "simplification" measure based in part on the small number of sentencings each year under §2N2.1. I discount that information somewhat, given that I have received it informally and it does not appear in a Commission or staff document. It is troubling, however, that such a rationale should be suggested, even informally, as it is obviously fallacious: a small volume of sentencings tells us virtually nothing about the usefulness of a particular guideline. For example, there are very few homicide prosecutions in the federal courts, but no one would rely upon that fact as a basis for abolishing the homicide guidelines.

⁵ For example, the American Law Institute's Model Penal Code, which has been widely emulated in state criminal codes and also used as a model for federal criminal code reform over the

referred to as "public welfare offenses"⁶ or "regulatory offenses"--terms that are used in contradistinction to "true" crime, based upon a finding of moral culpability.⁷

More significantly for present purposes, the entire rationale for accepting such "public welfare offenses" into our federal criminal law rests heavily on the assumption that "public welfare offenses" would involve relatively low and non-stigmatizing penalties, generally modest monetary fines based upon misdemeanor conviction, rather than imprisonment and the "infamy" associated with felony conviction.⁸ The distinction can be seen by comparing the two leading Supreme Court cases on each side of the divide, *United States v. Dotterweich*, 320 U.S. 277 (1943), which recognized the "public welfare offense" category specifically in the context of 21 U.S.C. § 331--one of the principal statutes now covered by Guideline §2N2.1--and *Morrisette v. United States*, 342 U.S. 246 (1952), which refused to extend the *Dotterweich* analysis to a statute prohibiting theft of government property--an offense that is cognate with the statutes now covered by Guideline §2F1.1. Justice Jackson's opinion for the Court in *Morrisette* is one of the most famous statements of the rationale for the requirement of mens rea for a criminal conviction:

"[T]hat an injury can amount to crime only when inflicted by intention is no provincial or transient notion. It is as universal and persistent in mature systems of law as belief in freedom of the human will and a consequent ability and duty of the normal individual to choose between good and evil. . . .

* * *

"Stealing, larceny, and its variants and equivalents, were among the earliest offenses known to the law that existed before legislation; they are invasions of rights of property which stir a sense of insecurity in the whole community and arouse public demand for retribution, the penalty is high and, when a sufficient amount is involved,

years, makes what the Code's comments describe as "a frontal attack on absolute or strict liability in the penal law," *Model Penal Code and Commentaries* § 2.05, Comment 1. Under the Model Penal Code, strict liability offenses are defined as "violations," which are not "crimes." *Id.* § 2.05.

⁶ See Francis B. Sayre, *Public Welfare Offenses*, 33 Colum. L. Rev. 55 (1933).

⁷ Supreme Court has endorsed this distinction. *Liparota v. United States*, 471 U.S. 419, 433 (1985).

⁸ This point is developed in depth, together with the associated moral and economic objections to strict liability in crime, by my 1993 article entitled *The Economics of Mens Rea*, 79 Va. L. Rev. 741, 785-804 (1993). Since that article, the Supreme Court has decided *Staples v. United States*, -- U.S. --, 114 S. Ct. 1793 (1994), which reaffirms the traditional presumption that all elements of all crimes require proof of criminal mens rea, unless a contrary indication plainly appears on the face of the legislation.

the infamy is that of a felony, which, says Maitland, is '... as bad a word as you can give to man or thing.'⁹

Thus, as the general principles are laid down by the Supreme Court, whether strict liability will be accepted as an adequate basis for criminal conviction depends in part upon the level and type of penalty imposed.¹⁰ Partly because of the relatively low and non-stigmatizing nature of the penalty for "regulatory" offenses, *Dotterweich*--as further developed in the later Supreme Court decision in *United States v. Park*, 421 U.S. 658 (1975)--accepted the reduced culpability standard of "responsible relation" to the violation in question. Even this standard does not completely dispense with all concept of fault, and its precise scope remains a subject of dispute in the lower federal courts.¹¹ But it is the lowest standard of culpability that has ever been accepted in federal criminal law.

In contrast, most of the statutes now covered by Guideline §2F1.1 are at the completely opposite end of the culpability spectrum; they require, as a prerequisite to conviction, proof beyond a reasonable doubt of what is called in criminal law a "specific intent"--a purpose not only to engage in the prohibited conduct, but to bring about a forbidden result. In most of those statutes--certainly all of the leading federal criminal fraud statutes, such as the mail fraud, wire fraud, travel fraud, and conspiracy to defraud--the requisite mens rea is "intent to defraud," which is a type of specific intent, and specific intent is the *highest* culpability level known to our criminal law.¹² Unlike the "regulatory" offenses, these offenses are almost inevitably felony convictions carrying substantial statutory imprisonment sentences. They are also an outgrowth of the same background of the common law of larceny, as consolidated in modern criminal codes in the law of "theft."¹³ Accordingly, they are essentially the same offense as was charged in *Morissette*.

⁹ 342 U.S. at 260.

¹⁰ This was an explicit part of the Supreme Court's rationale in its recent address to the mens rea doctrine in *Staples v. United States*, --- U.S. ---, 114 S. Ct. 1793 (1994), in which the Court relied, *inter alia*, on the severity of the prescribed penalty in ruling that a conviction for possession of an automatic weapon required proof of the defendant's knowledge that he possessed a weapon of the prohibited characteristics, and not merely a dangerous device.

¹¹ See generally John C. Coffee, Jr., *Does "Unlawful" Mean "Criminal"?: Reflections on the Disappearing Tort/Crime Distinction in American Law*, 71 B.U.L. Rev. 193 (1991).

¹² See 1 W. LaFare & A. Scott, *Substantive Criminal Law* § 3.5, at 315 (1986).

¹³ At common law, there was no crime of "fraud," as distinguished from "larceny by trick." The crime of "false pretenses" was added by Parliamentary statute in 1757. In most modern criminal codes, the common law crime of larceny is merged with the statutory crimes of false pretenses and embezzlement to comprise the consolidated offense of "theft." See 2 W. LaFare & A. Scott, *Substantive Criminal Law* §§ 8.1, 8.8 (1986).

Therefore, to consolidate offenses now covered by Guideline §2N2.1 with those now covered by §2F1.1 is to mix apples and oranges; it is to treat the *most* culpable defendants under exactly the same standards as the *least* culpable ones, with nothing that I can see in the resulting guideline to distinguish between the two. In doing so, the Commission would be obliterating important distinctions in culpability that have formed the moral foundations of our criminal law, and thereby, in my judgment, the Commission would be overreaching its limited mandate to rationalize sentencing policy without disturbing substantive standards of criminal liability, which are matters for the Congress, not the Commission.

This would be true even under the general principles I have stated. But in this particular context, the Commission also would be overstepping the bounds of distinctions made by the Congress itself in the very statutes under consideration here, primarily 21 U.S.C. §§ 610 and 676 in the case of meat products, and 21 U.S.C. §§ 331 and 333 under the federal Food, Drug and Cosmetic Act. In both instances, the statutes draw a distinction between a misdemeanor violation --the paradigmatic "public welfare offense"--and a more serious felony violation, in part on precisely the same mens rea distinction of "intent to defraud."¹⁴ That distinction--explicitly and specifically made by the Congress in the statutes in question--also would be obliterated by the consolidation of all offenses into the fraud guideline, which in my opinion would be a failure by the Commission to observe and apply the culpability and penalty distinctions made by the Congress, and therefore noncompliance with substantive statute law.

The specific statutory distinctions made by Congress provide an obvious and complete solution to the issue noted by the Staff Report (pages 12-13, 20, 22) of consistency in applying §2N2.1's pre-existing cross-reference to §2F1.1: that cross-reference should be applied only when the offense of conviction is the felony offense predicated on proof (or formal admission) or intent to defraud,¹⁵ and not to the misdemeanor violations. This solution follows the substantive statute more closely, and also is more consistent with the overall "charge offense" approach of the guidelines (see Section A.2, below). Moreover, it would avoid the undoubtedly controversial--and arguably unconstitutional--practice of sentencing misdemeanants as if they were felons, without proof beyond reasonable doubt, by admissible evidence, that in fact they had the requisite culpability to be considered felons. That is an unnecessary constitutional problem that the Commission should not foment.

¹⁴ The Staff Report notes this feature in describing the underlying statutes (*see* Staff Report, at 3-5), but then strangely ignores the distinctions in the remainder of its report. With all due respect to the staff, one is left with the impression that the authors of the report did not know what "intent to defraud" means in criminal law.

¹⁵ The other case of a felony conviction under these statutes is the repeat offender situation, which might call for a specific offense characteristic in §2N2.1, to the extent that the Commission determined that the matter was not adequately dealt with by the existing criminal history guidelines.

It appears from the Staff Report that the staff drew an undue inference from its examination of the reports of cases previously sentenced under §2N2.1. In a section of the Staff Report entitled "culpability," the staff purports to find that a high percentage of the cases "involved conduct that was purposeful or intentional" (page 9), and that this was based on "defendant admissions" (page 9). Apparently, this discussion is intended to suggest that most of the cases actually involved the higher level of culpability required for felony conviction. Even if this were true, it would not justify the abolition of the food and drug guideline, so long as there were even one case--or a potential case--of conviction without mens rea. But the staff's apparent conclusion does not follow from the data it examines, because the staff's analysis fails to distinguish "intent to defraud" from other forms of purposeful conduct, and, more importantly, it fails to account for the actual features of plea bargaining and guideline application in practice.

As against the staff's finding of "purposeful or intentional conduct," I would say "purposeful or intentional" as to what? A defendant might "purposefully" intend to violate a regulatory reporting or recordkeeping requirement, and that feature might call for a distinction in sentencing, but it says nothing about the formation of a specific intent to defraud, which is required under the fraud statutes and should be required before applying the fraud guideline, as the fraud guideline is predicated upon the assumption of such an intent, which is not the same as a generalized finding of intentional or purposeful behavior.

More fundamentally, I believe that the staff overemphasizes the significance of "defendant admissions" of culpability, which are very probably artifacts of plea bargaining in the shadow of the existing guidelines. As the Staff Report also notes, nearly all of these sentencings were plea bargains. The application notes to existing §2N2.1 indicate that "[t]he guideline assumes knowing or reckless conduct" (Application Note 1); otherwise, a downward departure may be warranted. Similarly, here as throughout the guidelines, "acceptance of responsibility" earns the defendant a 2-level reduction, and conventionally requires an acknowledgement of "guilt" in some sense. Thus, the typical structure of plea bargains under this guideline is obvious: the defendant admits "guilt," and thereby both gets the 2-level reduction and protects the prosecution against a downward departure; while the prosecution contents itself with a misdemeanor conviction--albeit with culpability "admitted"--while at the same time avoiding the expense and difficulty of proving the violation at trial. Similarly, in the more severe case of a potential felony conviction, the same basic bargain can be made, which presumably should be at a higher sentencing level.

Under the existing guideline structure, there is no incremental penalty for "admitting" purposeful or knowing conduct, and indeed there may be a discount through "acceptance." Under these conditions, we should not be surprised to find a high incidence of "admission." But that may have little to do with reality--especially the reality of proof at trial--if the guidelines structure is changed. It is a truism of guidelines sentencing that if the guidelines structure is changed, then the pattern of charges, defenses, and "admissions" also changes.

I understand that the regulatory agencies, and especially the FDA, generally defer criminal enforcement until there has been a previous warning or some other indication that the conduct in question is deliberate. But that sensible enforcement policy is a far cry from what state of mind actually can be proved beyond a reasonable doubt at a criminal trial. Indeed, that distinction accounts

for the entire category of "public welfare offenses," for which strict proof of criminal mens rea is dispensed with, in exchange for low, nonstigmatizing penalties. If the current proposal is approved, the practical result may well be to deprive the FDA and other agencies of that enforcement option, by driving potential penalties so far out of proportion to *provable* liability as to dramatically raise the rate of trials. In any case, it will largely destroy any incentive for the enforcement authorities to distinguish misdemeanor from felony violations, as the Congress intended them to do.

2. The General Approach of "Charge" Offense Sentencing. As indicated in my discussion of the culpability distinctions made by Congress in the underlying food and drug statutes, the Commission's current proposal appears to be inconsistent with the overall approach of "charge offense" sentencing that has been a basic feature of the federal sentencing guidelines since they were first promulgated in 1987. As has been noted in Chapter 1, Part A of the Guidelines since their inception, one of the fundamental policy choices made by the Commission was between a "real offense" and a "charge offense" sentencing system. The Commission initially attempted a "real offense" system that totally separates sentencing factors from the elements of charging statutes, but ultimately abandoned that system as impracticable and potentially unfair. As the Guidelines continue to state, "[i]n the Commission's view, such a [real offense] system risked return to wide disparity in sentencing practice" (*id.* at 5). This is a particularly troublesome consequence, as one of the fundamental objectives of the Sentencing Reform Act of 1984, which established the Commission, was to reduce unwarranted disparities and restore fairness and certainty to the federal sentencing process.

To avoid frustrating that objective, the Commission turned to a "modified charge offense" system of sentencing guidelines. Necessarily, such a system entails some degree of complexity in distinguishing among the many charge offenses involved in the federal system and occasional ambiguities in selecting among applicable guidelines. As experience is accumulated under the guidelines, monitoring data will call the Commission's attention to unanticipated application ambiguities, and the natural reaction will be to add still more application notes and cross-references, resulting in an even more complex structure. At some point, attention will be drawn to the problem of complexity itself, and there will be a natural tendency to "cut through" the complexities of choosing applicable guidelines by consolidating a larger range of charging offenses under a smaller number of guideline sections. In the extreme, all applicability problems can be solved easily by having only one guideline for all offenses, but that would transform the guidelines back into a "real offense" system, and thus reverse the fundamental policy choice. Short of the extreme, all proposals to consolidate previously separate guideline sections have the same tendency to reverse the fundamental policy choice in a piecemeal fashion, essential through a process of erosion. The danger is that, in reviewing each of the "simplification" proposals separately, the Commission inadvertently may back into a fundamental reversal of policy without full consideration of the policy choice itself.

Something like this process may be occurring in the case of the current proposal, which provides a particularly good illustration of the loss of refinement that can occur with "simplification" for its own sake. As I have indicated above, the particular application issue of applying the pre-existing cross-reference between § 2N2.1 and §2F1.1 can be solved very simply by closer attention to the distinctions among charging offenses that already have been made by the Congress in the

[196]

underlying food and drug statutes themselves: all that is required is an application note clarifying that cross-reference for an offense that "involved fraud" should be applied only where the offense of conviction was one the rested upon proof (or formal admission) of an intent to defraud. And yet, that obvious and straightforward solution, which is fully consistent with the "charge offense" approach, apparently was not even considered. An observer might conclude that the Commission had made a basic policy shift toward "real offense" sentencing, but I am aware that anything like that had been decided or even discussed. The more likely explanation is "simplification" for its own sake, without considering the broader policy issue.

In either case, the practical result is equivalent to a basic shift of policy. By consolidating §2N2.1 into §2F1.1, we would mix a wide range of offenders and offenses under the same guideline: misdemeanants with felons, the least with the most culpable, purely commercial harms with personal injuries or risks to public health or safety, and widely disparate underlying statutory policies. As can be seen, ultimately this does not reduce overall complexity; it simply shifts the complexity from guideline selection to the application of increasingly complex and broad-ranging individual guideline sections. I would predict that many observers would find it unseemly that offenses against statutes motivated by considerations of public health and safety would be sentenced under a guideline designed initially for commercial frauds; they will demand modifications to put health and safety risks into the guideline text itself. The beginnings of this process already can be seen in the Commission's own proposal of a departure consideration for injury risks, and its request for comments on an attenuation of the economic loss concept that heretofore has been central to the fraud and theft guidelines, focused as they are on property crimes. Once that process develops, the "fraud" guideline becomes less focused on fraud; it becomes, in effect, a generic guideline tending toward the "real offense" system that the Commission rejected ab initio.

By raising this point, I do not mean to comment on the overall merits of "real offense" versus "charge offense" sentencing. The Commission may wish to re-examine that fundamental policy choice. But I see no indication in the record that the Commission has done so, or intends this current proposal as a basic policy shift. That is a very large subject that deserves separate and complete consideration in its own right. My concern is that the Commission unintentionally may be backing into a major policy shift without ever having considered the subject at all.

3. The General Approach to "Regulatory" Offenses. I have a similar concern regarding the implications of the current proposal as indicating yet another deviation from the fundamental policy choices on which the existing guidelines' structure rests, which is the overall approach to "regulatory" offenses. Current §2N2.1 is only one of several guidelines based on the same overall approach, which was first formulated in 1987 and continues to be stated in Chapter 1, Part A of the current Guidelines (pages 8-9). That approach describes a four-tiered structure for dealing with regulatory offenses, in order to distinguish differing levels of harm and culpability in a way that parallels the substantive law's distinction of "public welfare offenses" from more serious crimes. As food and drug offenses are the widely-recognized paradigm for "regulatory offenses," the withdrawal of §2N2.1 may be interpreted as a signal that the Commission intends to dismantle the guidelines' overall approach to "regulatory offenses" more generally. As in the case of "charge offense" sentencing, that may or may be the Commission's intent. But from what I have seen, I am unaware

of any general policy decision by the Commission on this subject, and, once again, I do not believe that the Commission should place itself in the position of backing into a major policy shift on an ad hoc, piecemeal basis.

If the Commission wishes to re-examine its overall approach to regulatory offenses, I believe that the appropriate way to proceed is to begin with the general principles stated in §4(f) of Chapter 1.A of the existing Guidelines. As a matter of law, that provision is a "policy statement" that the courts are required to consider--and all participants have a right to rely upon as being an accurate statement of Commission policy--until it is explicitly modified. The current proposal is inconsistent with that statement, because it proposes to remove the purely technical level of offense from the sentencing structure. That move would have very profound implications for the law enforcement options available to regulatory officials, even within the immediate context of food and drug offenses, but especially if it were generalized to such matters as currency reporting, environmental recordkeeping offenses, and the like. I see no indication that any of those implications have been considered by the Commission or its staff, or discussed with the regulators or the regulated industries. From this perspective, the current proposal is precipitous and ill-considered simply as a matter of orderly procedure, quite aside from its underlying merit, which, as I have indicated above, is questionable.

In any case, I believe that any changes to specific guidelines implicating the overall approach to regulatory offenses would be premature unless and until proposed modifications to the general principles are exposed for public comment and debate, and full consideration and approval by the Commission.

B. Organizational Sentencing

The Commission's notice also proposes to extend the provisions of Chapter 8 to food and drug offenses, which were omitted from Chapter 8 as promulgated in 1991. Obviously, the wisdom of this change will depend to a large extent upon the resolution of the issues concerning the survival of §2N2.1, as Chapter 8 employs Chapter 2 offense levels as a factor in determining organizational sanctions. If the Commission decides to defer consideration of the Chapter 2 changes--as I believe it should--then a deferral of any related Chapter 8 changes also would be in order.

It is difficult to comment on this subject, as I am unfamiliar with the rationale for excluding food and drug offenses from the original Chapter 8. The Staff Report suggests that the application of Chapter 8 guidelines to food and drug offenses would produce essentially the same results as non-guideline law, for the small number of cases that the staff examined (Staff Report, at 19-20). However, given the small number of cases available, I am not sure that this is a good argument for extending Chapter 8 at this time. If the rationale for excluding food and drug offenses initially was the unpredictability of consequences, then we still do not have enough information to make confident predictions. Moreover, the Staff Report does not provide even anecdotal evidence of serious problems with non-guideline sentencing. In this context, the Commission might be best advised to let well enough alone, as compared with the unpredictable alternative.

One of the possible adverse effects of Chapter 8 as applied to food and drug offenses is that its concepts of compliance programs may or may be compatible with the regulatory compliance standards and procedures already imposed by the Food and Drug Administration and other regulatory agencies. However, I see nothing in the Staff Report to indicate that this issue was reviewed with the appropriate regulatory officials. At a minimum, and aside from all other issues, that reviewed should be completed before the Commission considers applying Chapter 8 standards in this heavily regulated environment, as the application of the sentencing guidelines' incentives to these firms may have the unintended consequence of undermining the regulatory agencies' efforts.

C. Loss, Gain, and "Regulatory Fraud"

Finally, the Commission's notice calls for "comment as to whether 'gain' should be a substitute for 'loss' when the essence of the offense is fraud against regulatory authorities with no economic loss," 61 Fed. Reg. 83. No specific guideline language or context is proposed. The issue was raised in the specific context of food and drug offenses by the Staff Report (pages 13-15), but the Commission's notice appears to contemplate application to all offense sentenced under §2F1.1, which itself would give the concept a very broad application, and the concept would have the tendency to migrate—I am inclined to use the term metastasize, given its destructive potential-- elsewhere in the guidelines. I would strongly urge the Commission to take no action on this concept during the 1996 amendment cycle, because this is potentially the most far-reaching aspect of the current proposal, and I do not believe that the Commission has begun to consider its true consequences.

Like some of the other issues, this question may seem at first to be a technical matter of guideline application. But it is not. To adopt such a concept would be a radical shift in the entire focus of our sentencing system, both before and during the guidelines era. I am aware that "gain" is referred to in some portions of the existing guidelines, but always as a proxy for "loss." The current proposal would totally disconnect the two, by contemplating a situation of no economic loss (or even a risk of loss). That is a radical change, and a potentially destructive one, especially in the suggested context of "regulatory fraud," which is probably the worst imaginable context in which to adopt such a concept.

Even as a general proposition, sentencing on "gain" rather than "loss" is wrong as a matter of theory and infeasible as a matter of practice. I have made these points many times, in my published articles,¹⁶ in Congressional testimony,¹⁷ and in internal memoranda to the Commissioners when I was

¹⁶ See Parker, *Criminal Sentencing Policy for Organizations: The Unifying Approach of Optimal Penalties*, 26 Am. Crim. L. Rev. 514, 554-70 (1989); Parker, *Rules Without: . . . : Some Critical Reflections on the Federal Corporate Sentencing Guidelines*, 71 B.U.L. Rev. 397, 408-10 (1993); Parker, *The Economics of Mens Rea*, 79 Va. L. Rev. 741, 754-62 (1993).

¹⁷ The clearest statement of the point from the perspective of practical policy formulation can be found in my post-hearing statement submitted in connection with my 1990 testimony before the

counsel to the Commission. The fundamental point is that criminal prohibitions are never intended to outlaw "gains." They are always intended to prevent harms, which is another name for "loss." Thus, focusing sentencing policy on "gain" turns substantive legal policy upside down, by punishing something that the legislature did not mean to punish, and failing to punish what the legislature did mean to punish. While it is superficially tempting to believe that the deterrent policy of sentencing is served by focusing on offenders' gains, that is always the wrong focus. At the extreme, the logic implies that we impose the death penalty for a parking violation, if the offender saved a life by overtime parking. Even short of the extreme, that is not very good logic, and it is not the logic of criminal prohibitions, which set the penalty for overtime parking based on the social harm of overtime parking, and not on the basis of what offenders may "gain" from overtime parking.

As troublesome as the focus on "gain" is in general, it is all the more pernicious as applied to the concept of "fraud against regulatory authorities with no economic loss." Assuming that "gain" would in essence be "cost saved" by noncompliance with regulations, notice the incentive effects on regulatory and enforcement authorities: higher penalties, which presumably are what enforcers will seek in our adversarial system, will follow from more and more burdensome regulatory requirements. In an era when we already have an uproar over the burden of government regulation, we would have the Sentencing Commission giving regulators a very explicit incentive to impose even more burdensome regulations--not as necessary to insure public health and safety, but solely to raise the threatened penalty level. Now consider the incentives of potential violators: adopting this concept would tell them that if they are going to violate, they should make sure that they hurt someone economically; that way, they avoid the "no economic loss" condition. Once again, the incentive structure is upside down, in much the same way as it would be if the penalty for robbery were the same as--or, to make the analogy more direct-- more than the penalty for murder. Obviously, sentencing law should give a differential incentive for regulatory violators not to hurt anyone, by giving a lower sentence if no one is hurt.

Finally, this aspect of the proposal, more so than the others, threatens to involve the Commission in what is, in effect, the legislation of an entirely new offense of "regulatory fraud," which again would overstep the bounds of the Commission's limited powers. If there is to be such an offense, it should be legislated by the Congress, not the Commission. And if it were legislated, its rationale would rest on the harm to the governmental program involved--in other words, the "loss," whether conventionally "economic" or not--and not on violators' "gains."

D. Summary

Overall, the current proposal on food and drug offenses is insufficiently developed to be considered for approval by the Commission. The proposal rests on staff work that failed to recognize

House Subcommittee on Criminal Justice. *See Oversight on the United States Sentencing Commission and Guidelines for Organizational Sanctions: Hearings Before the Subcommittee on Criminal Justice of the Committee on the Judiciary, House of Representatives, 101st Cong., 2d Sess. 488-51 (1990).*

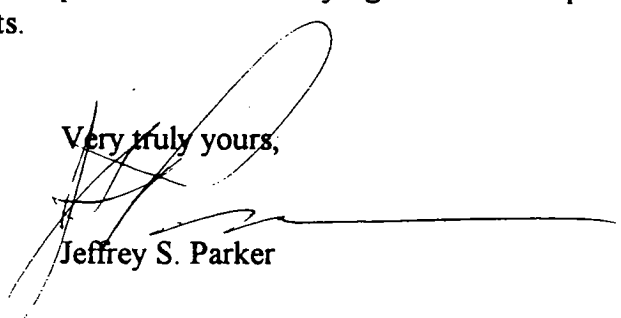
the fundamental nature of the underlying offenses as strict liability and regulatory crimes, and failed to observe the culpability and grading distinctions established by the Congress in the statutory provisions. The staff's analysis also fails to account for the effects of the plea bargaining process on observed culpability "admissions" by defendants. Furthermore, the staff's analysis does not support or recommend the current proposal to abolish the separate food and drug guideline. Rather, the staff focused only on a cross-referencing issue that can be resolved easily by a minor amendment to the text or commentary of §2N2.1.

More generally, the proposal has profound implications for the broader structure created by the Guidelines' basic approach of "charge offense" sentencing and the Guidelines' basic approach to regulatory offenses. There is no indication that either the staff or the Commission has perceived or considered these implications. In particular, the current proposal is inconsistent with the Commission's existing statement of policy regarding regulatory offenses, to which no amendment has been proposed. In both instances, the broader issues deserve full and separate consideration in their own right.

A similar situation exists with respect to the request for comment on the question of using "gain" rather than "loss" in cases of "fraud against regulatory authorities with no economic loss." Adopting such a concept would again be a profound and potentially disastrous shift in basic sentencing policy that deserves far more extensive consideration than it apparently has received to date.

For these reasons, the Commission should not proceed with the proposed food and drug amendments during the 1996 cycle. Instead, the Commission should withdraw its notice of proposed amendment, and direct further study of the subject both in detail and in the broader context of overall guidelines structure, in order to insure that future amendments, if any, to the food and drug guidelines are both consistent with the Commission's explicit and considered judgment on basic policy questions and well-supported on their own merits.

Very truly yours,


Jeffrey S. Parker

cc: Pharmaceutical Research and Manufacturers of America