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March 11, 2003

The Honorable John Gleeson
United States District Judge
United States District Court
Eastern District of New York
225 Cadman Plaza East
Brooklyn, New York 11201

RE: U.S.A. v. Jason Vale, 02 CR 466

Your Honor:

We are scheduled to argue the Defendant's Motions on March 14, 2003, and write to address two issues. The first concerns the Defendant's Motion to Recuse the Prosecutor. The second concerns the Defendant's Motion for a Bill of Particulars.

Motion for Recusal of Prosecutor

In its reply brief, the government makes a point that we believe is contrary to the applicable law.

The government attorney argues that his role as both an attorney in the civil action and prosecutor in the criminal action presents no conflict. One reason for that, according to the government, is because Mr. Vale's injunction is final and he may not modify it. See United States' Memorandum of Law in Opposition to Defendant Vale's Pre-Trial Motions, n. 5.

We disagree. Mr. Kleinberg's position as both civil and criminal prosecutor of Mr. Vale continues to prejudice Mr. Vale in any efforts to modify the injunction. Under the law it is never too late to modify an injunction proscribing future conduct such as this in certain circumstances.

Federal Rule of Civil Procedure 60(b) contemplates that remedial orders may be modified:

> On motion and upon such terms as are just, the court may relieve a party or a party's legal representative from a final judgment, order, or proceeding for the following reasons: ... (5) ... it is no longer equitable that the judgment should have prospective application; or (6) any other reason justifying relief from the operation of the judgment.

See also U.S. v. Secretary of Housing and Urban Development, 239 F.3d 211, 216 (2d Cir. 2001). Furthermore, because consent decrees are injunctions, their modifications are reviewed for abuse of discretion only. Id. (*quoting* Juan F. v. Weicker, 37 F.3d 874, 878 (2d Cir.1994), cert. denied, 515 U.S. 1142, 115 S.Ct. 2579, 132 L.Ed.2d 829 (1995)).

The text of Federal Rule 60(b) places a one-year time limitation only upon three bases for modification not applicable here. See F.R.C.P. 60(b) ("The motion shall be made within a reasonable time, and for reasons (1), (2), and (3) not more than one year after the judgment, order, or proceeding was entered or taken.").

A change in legal climate is just one example of a circumstance under which this injunction may be modified. See also U.S. v. Eastman Kodak, 63 F.3d 95, 102 (2d Cir. 1995) ("Of course, cases may arise in which modification or termination of a consent decree is appropriate even though the purpose of the decree has not been achieved. For example, there may be significant changes in the factual or legal climate.")

To the extent that the government views the term "promotion" as used in the injunctions as prohibiting Mr. Vale's right to speak freely about his belief in the healing properties of apricot seeds and amygdalin (as opposed to actual sale or distribution), Mr. Vale may wish to seek clarification or modification of the injunctions. While we do not concede that the term "promotion"–a word *not* found in the relevant regulatory statute or regulations on the subject–does reach to free speech, we have no way of knowing until the government puts on its case how they define the term. Do they mean advertising for sale or distribution? Or are they saying that Mr. Vale cannot cite his Bible verses and his personal experiences when talking to others about apricot seeds and amygdalin?

Interestingly, cursory research reveals a series of cases that would appear to undermine any argument that the government would have to restrict Mr. Vale's right to speak freely about his beliefs. We point out the following cases, decided *after* the Permanent Injunction issued in this case.

1. Ashcroft v. Free Speech Coalition, Inc., 122 S.Ct 1389 (2002) – action brought by pornographers to enjoin application of Child Porn Prosecution Act against purveyors of virtual child pornography. Supreme Court held that the potential harms were too attenuated from the proscribed speech and struck the application as overbroad and unconstitutional in violation of

First Amendment. "[T]he Court's First Amendment cases draw vital distinctions between words and deeds, between ideas and conduct . . . The government may not prohibit speech because it increases the chance an unlawful act will be committed 'at some indefinite future time." 122 S.Ct 1389, 1403.

2. Conant v. Walters, 309 F.3d 629 (9th Cir. 2002) – in action by physicians seeking to recommend medical marijuana to patients to enjoin federal government from revoking physicians' license or conducting investigations that might lead to such revocation, court upheld portions of injunction finding that the government policy of discouraging open communication between doctor and patient interfered with First Amendment rights.

3. Thompson v. Western States Medical Center, 122 S.Ct 1497 (2002) – in action brought by pharmacies for declaratory relief against FDA Modernization Act, prohibiting advertising and *promotion* of particular compounded drugs, Supreme Court held these provisions were unconstitutional restrictions on commercial speech.

Furthermore, there have been suggestions in the media about ways in which the FDA and the present administration continues to rethink its policies, as well as suggestions that these bodies may be more generous toward people who advocate alternative, particularly religious-based therapies. See, e.g., "Stung By Courts, F.D.A. Rethinks Its Rules," New York Times, October 15, 2002 (copy attached); Dowd, M. "Tribulation Worketh Patience," New York Times, Op-Ed, October 9, 2002 (copy attached).

We quote these cases only to point out possible arguments Mr. Vale might have if he wanted to negotiate with government concerning the terms of the Permanent Injunction, particularly as to the term "promotion." Mr. Kleinberg's position as prosecutor and representative of the FDA, it seems to us, gives him continued advantage in the criminal case and prejudices Mr. Vale in any future actions he may wish to take in the civil case.

Motion for Bill of Particulars

On February 14, 2003, we renewed and modified our request for a Bill of Particulars to address the Superceding Order to Show Cause. The government still refuses to provide the requested particulars.

For the Court's review, the following requests are directed to the Superceding Order to Show Cause. We respectfully incorporate the arguments made in our motion.

1. As to each of Counts One and Two of the Superceding Order to Show Cause, please state the following:

a) the date(s) upon which the government contends that the defendant directly or indirectly introduced or caused to introduce into interstate commerce, held for sale after introduction into interstate commerce, manufactured, processed, packed, labeled, or distributed any product that the government contends is amygdalin, laetrile, Vitamin B-17, and apricot seeds;

b) the person or persons whom the government contends was aiding, abetting, counseling, commanding, inducing, procuring, and causing to perform each of the foregoing acts;

c) the person(s) and/or address(es) to whom the government contends that the defendant introduced or caused to introduce into interstate commerce, held for sale after introduction into interstate commerce, manufactured, processed, packed, labeled, or distributed any product that the government contends is amygdalin, laetrile, Vitamin B-17, and apricot seeds;

d) The phone numbers and web sites that the government contends were contacted that led to the introduction into interstate commerce, holding for sale after introduction into interstate commerce, manufacturing, processing, packing, labeling, or distributing of any product that the government contends is amygdalin, laetrile, Vitamin B-17, and apricot seeds;

e) To the extent that the government claims that the defendant indirectly or directly "caused" products to be introduced into interstate commerce, held for sale after introduction into interstate commerce, manufactured, processed, packed, labeled, or distributed (as opposed to performing any of these actions himself), please state the names and addresses of all persons or entities through whom the government contends any of these actions were performed with respect to amygdalin, laetrile, Vitamin B-17, and apricot seeds, and the dates of the actions.

f) As to each Count, please state the "SAMPLE NUMBER," as referred to in the Memorandum Results of Analysis dated June 5, 2002, that corresponds to any product that the government contends is implicated in that Count;

g) also state from where and when this product, as referred to by SAMPLE NUMBER, was seized or recovered.

2. As to each of Counts Three and Four of the Superceding Order to Show Cause, please state the following:

a) the date(s) upon which the government contends that the defendant promoted, over the internet or otherwise, amygdalin, laetrile, Vitamin B-17, and apricot seeds as a cure, treatment, mitigation, and prevention of cancer;

b) the phone numbers, web sites, publications, or any other medium through which the government contends that the defendant promoted, over the internet or otherwise, amygdalin, laetrile, Vitamin B-17, and apricot seeds as a cure, treatment, mitigation, and prevention of cancer

c) the exact words, sentences, phrases and/or images that the government contends constitute promotion over the internet or otherwise, amygdalin, laetrile, Vitamin B-17, and apricot seeds as a cure, treatment, mitigation, and prevention of cancer.

d) the person or persons whom the government contends that the defendant directly and indirectly was aiding, abetting, counseling, commanding, inducing, procuring, and causing to promote.

Thank You for Your attention to this matter.

Respectfully Submitted,

Jan Rostal
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RE: U.S.A. v. Jason Vale, 02 CR 466

Your Honor:

We write in response to the government's adjournment letter dated February 20, 2003 ("Kleinberg Letter"). By that letter, the government opposes a bench trial because it would limit Mr. Vale's sentencing exposure to six months.

The Court should be aware of our position, which is that the law supports Your Honor's discretion to hold a bench trial if the maximum exposure is six months in custody. Taylor v. Hayes, 418 U.S. 488 (1974) (defendant not entitled to a jury trial on criminal contempt charges where no more than a six months' sentence had actually been imposed). The Supreme Court has long held that "petty contempt, like other petty criminal offenses may be tried without a jury when the penalty actually imposed does not exceed six months or a longer penalty had not been expressly authorized by statute." Id. at 2701 (citing Bloom v. Illinois, 391 U.S. 194 (1968)).

Therefore, the defense position is that, regardless of the statutory maximum (of which there is none), the Court can indeed trump Mr. Vale's right to a jury trial by limiting the potential sentence to six months.

Nevertheless, the government argues that "a prison term of only six months would be inappropriate in this case." Kleinberg Letter, at 1. We disagree.

We believe a bench trial makes sense. Besides serving the Court's interest in vindicating its authority and the public's interest in prosecuting this case, there are several other justifiable reasons for limiting the sentencing exposure in this case.

I. A Six Month Maximum Penalty Is Not Inconsistent with the Guidelines or the Relevant Statutes

As in any other criminal case, the threshold sentencing question here–should the case get to a sentencing phase--is which guideline applies. The Statutory Index to the Guidelines Manual (Appendix A) directly tracks charges brought under 18 U.S.C. §401 to USSG § 2J1.1 (entitled "Contempt"), which in turn tracks to USSG §2X5.1 (entitled "Other Offenses"). That guideline directs the Court to apply the most analogous offense guideline, or in the absence of such, the provisions of 18 U.S.C. § 3553(b). See United States v. Cefalu, 85 F3d 964 (2d Cir 1996)

The conduct underlying the contempt charged here–that of selling and promoting apricot seeds–**is directly proscribed by statute in 21 U.S.C. §331.** Congress enacted a penalty provision in the Federal Drug and Cosmetic Act (FDCA), 21 U.S.C. §333(a), which states that "any person who violates a provision of section 331 shall be imprisoned for not more than one year or fined not more than $1000 or both." The potential penalty increases to three years upon a second conviction or if the offense involves an intent to defraud or mislead. 21 U.S.C. §333(b).

Interestingly, both 21 U.S.C. §331 and §333(a) point to USSG 2N2.1 (entitled "Violations of Statutes and Regulations Dealing With Any Food, Drug, Biological Product, Device, Cosmetic, or Agricultural Product"). The base offense level under USSG 2N2.1 is 6. Assuming that Mr. Vale has no more than one criminal history point, and the discovery suggests he does not, he is in Criminal History Category I, with a corresponding guideline range of 0 to 6 months.

There is a cross-reference in USSG 2N2.1 "if the offense involved fraud" to §2B1.1 (Theft, Property Destruction, and Fraud). Nevertheless, even if the government could prove beyond a reasonable doubt that Mr. Vale violated the injunction, it cannot plausibly argue that Mr. Vale's conduct amounted to "fraud" in any common sense of the word.

This is not a case in which a seller peddled a product claiming it to be one substance, say aspirin, when it was in fact a sugar pill. People who bought Mr. Vale's apricot seeds and amygdalin (apricot seed extract) over the years were well informed that they were buying just that–apricot seeds and amygdalin. The crux of the FDA quarrel with Mr. Vale is that the agency disagreed with claims that apricot seeds or amygdalin has any effect on cancer--either Mr. Vale's or anyone else's. That does not make out a case of fraud. At most, proof of the allegations in the Order to Show Cause amount to proof of a violation of 21 USC §333(a)–which is a regulatory crime.

We believe that the term "fraud" should not be construed in the abstract way that the government might like in order to apply the higher guidelines of USSG 2B1.1 in this particular case. The Second Circuit, in discussing the landmark Supreme Court decision of McNally v.

United States, 483 U.S. 350 (1987), has said that what the Supreme Court meant in its discussion of fraud was that

> the concept of fraud . . . was not satisfied by a scheme to deprive the victim of abstract values such as the right to honest government, but required a scheme aimed against the monetary or property interests of the victim.

Porcelli v. United States, 303 F.2d 452, 457 (2d Cir. 2002) (emphasis added). The court further added:

> In McNally, the defendants, a public official of the Commonwealth of Kentucky and another person affiliated with him, were charged with violating [the federal mail fraud statute] by participating in a secret scheme to require the insurance agency that sold insurance to the State to share its commissions with companies in which defendants had an interest. The theory of the prosecution was that defendants' participation in this kick-back scheme "defrauded the citizens and government of Kentucky of certain 'intangible rights,' such as the right to have the Commonwealth's affairs conducted honestly." 483 U.S. at 352, 107 S.Ct. 2875. There was no showing, nor was the jury charged, that defendants' scheme had deprived Kentucky of money or "that in the absence of the alleged scheme the Commonwealth would have paid a lower premium or secured better insurance." Id. at 360, 107 S.Ct. 2875. The Supreme Court overturned the convictions on the grounds that [the federal mail fraud statute] does not encompass schemes that deprived citizens of their right to honest and good government. It held that the "the words 'to defraud' commonly refer 'to wronging one in his property rights by dishonest methods or schemes,' and 'usually signify the deprivation of something of value by trick, deceit, chicane or overreaching.' " Id. at 358, 107 S.Ct. 2875 (citation omitted).
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> The Court's point was that the term "fraud" as used in [the federal mail fraud statute] was limited to its familiar common law meaning, which involved using falsity to do the victim out of money or property interests--not the expansive meaning adopted by the Courts of Appeals encompassing a deprivation of abstract values like honest government. There was no issue before the Court as to whether the victim's lost financial interest needed to be a vested right. Where the Court said that "the words 'to defraud' commonly refer 'to wronging one in his property rights,' " id. at 358, 107 S.Ct. 2875 (emphasis added), there was no suggestion that the Court meant anything different from doing one out of "his property *interests*." . . . The Supreme Court meant that [the federal mail fraud statute] did not *expand* the familiar notion of fraud into deprivations of abstract values.

Id. (Emphasis added).

The government theory seems to be that Mr. Vale defrauded the FDA by failing to submit to the FDA application procedures for a new drug, and continuing to sell the product, or aid and

abet others in doing so, in the face of the injunction. If disobeying an injunction amounted to fraud, every indirect contempt case would result in application of the fraud guidelines.

We recognize that there are a few cases outside the Second Circuit suggesting that violations of 21 U.S.C. §333 can lead to application of USSG §2F1.1 guidelines, although these do not appear to address McNally. See United States v. Andresen, 45 F.3d 217 (7th Cir. 1995). For example, in Andresen, the defendants pleaded guilty to distributing veterinary drugs without the proper licensing or approval from the FDA with the intent to defraud and mislead the FDA. While the Seventh Circuit found that a regulatory agency could be victimized by fraud, it disagreed with the government that the amount of loss could be calculated by the defendants' gain. As in Mr. Vale's case, there was no evidence that the defendants' customers or consumers suffered any monetary loss, and thus the defendants' gain could not be used as a proxy for loss when calculating the adjustment under USSG 2F1.1(b)(1). Id. at 221.

Thus, even under the analysis applied in Andresen, the guideline would remain at level 6. See USSG 2B1.1.

II. The Criminal Statute Directly Proscribing the Activity that the Government Asserts Amounts to Criminal Contempt Should Guide the Decision as to Punishment

The contempt statutes appear to limit the penalties in several ways. Under 18 USC §402, if the contempt also constitutes a crime the term of imprisonment is limited to six months, unless the contempt is in disobedience of a lawful order or decree in any suit brought on behalf of the United States. In that case, the defendant may be punished "in conformity to the prevailing usages at law." 18 U.S.C. §402.

This case falls within the exception to the exception under 18 USC §402, i.e. there is no statutory limit to the sentence except for the "prevailing usages at law." But what are these "prevailing usages at law?"

Congress has already determined that the appropriate penalty for the sale of an unapproved drug is a maximum of one year. 21 U.S.C. §333(a). This statute seems to be the most compelling evidence of the "prevailing usages at law" and should provide some guidance as to the penalty under both the guidelines and 18 U.S.C. § 3553(b).

III. Mr. Vale's Case Presents Unique and Compelling Facts and Circumstances That Mitigate Any Punishment the Court Might Impose

Mr. Vale is a three time cancer survivor who attributes his recovered health to changes in his diet. These changes include the ingestion of apricot seeds and amygdalin (a concentrated source of the chemical compound found in these seeds).

Mr. Vale is a "true believer." He came upon his beliefs, as he describes it, through prayer

and personal experience. His first bout with cancer was at age 18 when he was diagnosed with a rare form of the disease called the Askin's Tumor. He underwent an operation for removal of the tumor and at first refused follow-up treatment. When the cancer was re-discovered a year later he underwent combined chemotherapy and radiation treatments. Two months later he had lost 40 pounds and sick.

Seven years later doctors discovered another malignant tumor in his kidney. Just before he was to have his kidney removed, he decided to try alternative forms of medicine. (He explains that he walked off the pre-op table at the last minute). He read the popular book "World Without Cancer" by G. Edward Griffin, which presented the theory that cancer is a disease caused by nutrient-deficiencies, particularly of a chemical compound known as 'nitriloside' contained in certain foods such as apricot seeds, millet, lima beans, and wheat grass. (World Without Cancer is still sold in reputable book stores and on internet sites such as Amazon.com). Mr. Vale underwent an intensive dietary change, and Cat scans showed the tumor shrinking (without traditional treatments). He never had the kidney removed.

Mr. Vale has stayed alive for nine years since walking off the operating table without traditional treatments. He says that, as an experiment, he has taken himself off his diet (including apricot seeds) for periods of time, during which the pain returns.

His beliefs are also driven by others' accounts of dietary relief from cancer, and also by religious conviction. On his website, www.ApricotsFromGod.com, he cited numerous Bible verses that support certain dietary habits, most relevant in this case the injection of seeds. See, e.g. www.apricotsfromgod.com/news.htm (Attached).

We are also, candidly, troubled by another aspect of the case. The bulk of the government's proof in the case (as evidenced by the discovery turned over to date) appears to have been recovered during a search of the defendant's home conducted one month before the signing of the Consent Decree of Permanent Injunction.

If the government had probable cause to believe that Mr. Vale was violating the Preliminary Injunction a month before it entered into the Permanent Injunction with Mr. Vale, why did they enter into an agreement with him? Why not seek to hold him in contempt for violating the Preliminary Injunction? Why not charge him immediately with a violation of 21 USC 333? It seems that entering into the Permanent Injunction, with full knowledge that he had been (in their view) violating the Preliminary Injunction is inconsistent with the sort of good faith and fair dealing that is supposed to mark contract negotiations.

IV. We Are Aware of No Similar Cases in Which Criminal Contempt Convictions have Resulted in Sentences of More Than Six Months

A search of Westlaw has produced no known cases involving violations of criminal

contempt for selling apricot seeds, amygdalin, or laetrile. There was one civil contempt case. United States v. Articles of Food and Drug, 449 F.Supp 497 (D.C. Wis. 1978).

A LEXIS search of news databases revealed one case involving a violation of 21 U.S.C. §331 and 333. United States v. Kenneth N. Michaelis, CR 2-00-115 (S.D. Ohio). In that case, the defendant pleaded guilty to two counts of distributing an unapproved new drug (Laetril and hydrazine sulfate), and was sentenced to 6 months in a halfway house.

At least based on what we can find, it does not appear that anyone, anywhere has been sentenced to prison time for selling apricot seeds, amygdalin, or laetrile. If the government gets what it wants, Jason Vale would be the first.

Conclusion

We believe that the Court has the legal authority to trump Mr. Vale's right to a jury trial by limiting the sentencing exposure to six months. We also believe that this procedure would be consistent with the guidelines, the prevailing usages at law, and the punishment imposed nationwide for this crime.

For all of these reasons, we ask the Court to determine that six months is the maximum sentence it would impose in this case and proceed to a bench trial.

Thank You for Your attention to this matter.

Respectfully Submitted,

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