

J. DAVID ASH, ESQ.  
ATTORNEY AT LAW

Rec'd 3/12/03

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July 18, 2001

Dr. Benjamin Sweatz, Acting Associate  
Commissioner for Regulatory Affairs  
Food and Drug Administration  
U.S. Department of Health and Education  
Rockville, MD 20857

RE: *United States of America v. Satish R. Shah*, Docket No. 93N0349

Dear Dr. Sweatz:

Please be advised that I represent Mr. Shah in his efforts to re-open his permanent debarment case. Mr. Shah is requesting that the application for special termination of debarment be reviewed and his case be re-opened. For your information, I am enclosing a copy of a letter received by Mr. Shah from Gary J. Dykstra, the former acting associate commissioner for regulatory affairs. The central point of the letter is that, in order to have the special termination approved, Mr. Shah will have had to establish that he provided substantial assistance in the investigation or prosecution of certain offenses. I understand that concept is a matter of law, and the agency has no discretion.

I would hope that you would take a moment to review Mr. Shah's case.

I propose to you that Mr. Shah was of significant substantial assistance in terms of the government bringing about its case against Par Pharmaceuticals. I am enclosing, once again, copies of correspondence from various agents which reflect the level of his assistance. I would go further and indicate to you that it was Mr. Shah who originally contacted the FDA regarding the irregularities he discovered at Par. Mr. Shah was, without doubt, the central figure in the initial stages of the investigation. He corresponded and spoke directly to investigators from the FDA, and his assistance was, in my mind, unparalleled in terms of the completion of the investigation.

93N-0349

LET 12

4367 HOLLINS FERRY ROAD, SUITE 2-C - BALTIMORE, MARYLAND 21227-3400

T-104 P.013/018 F-451

301-480-2255

From-DHHS/PHS/FDA

05:07pm

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Dr. Bernard Sweast  
July 18, 2001  
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Obviously, you are aware that Mr. Shah was convicted in the Par Pharmaceutical conspiracy case in the early '90s in U.S. District Court. Mr. Shah maintains that it was not his intent to act contrary to the dictates of the law; however, he has accepted the results of his trial, and is well beyond his personal difficulties with his incarceration.

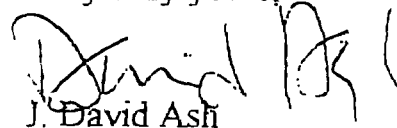
It is my opinion that the emphasis on Mr. Shah's case has always been directly related to his conviction. I understand the government's and your agency's position on that concept; however, I must say that Mr. Shah has been steadfast in his belief that he was not attempting to break any FDA regulations, or, in fact, any federal law.

Be that as it may, the uniqueness of Mr. Shah's assistance and cooperation with the FDA has consistently been understated. Mr. Dykstra in his letter indicates that Mr. Holland noted that "Mr. Shah took the initiative in contacting authorities and continued to cooperate in the investigation." Certainly, Mr. Holland's dealings with Mr. Shah pre-dated the indictments being issued. Most respectfully, I would indicate that all investigations and cooperation which were initiated by one such as Mr. Shah would pre-date any indictments. The fact that Mr. Shah would not plead guilty to the offense the government alleged should not, in my mind, preclude him from having the special termination considered.

I would greatly appreciate it if you would be so kind to contact me at your convenience to review this matter in detail.

Obviously, Mr. Shah made a mistake; however, his efforts on behalf of the government should be given consideration in his attempts to pursue this matter.

Very truly yours,

  
J. David Ash

JDA em  
00-137  
swest20718011at wpxd  
Enclosures



DEPARTMENT OF HEALTH &amp; HUMAN SERVICES

Public Health Service

MAR 17 1999

Food and Drug Administration  
Rockville MD 20857**VIA CERTIFIED MAIL  
RETURN RECEIPT REQUESTED**

Satish R. Shah  
66 Lockwood Place  
Clifton, NJ 07012

Re: Docket No. 93N-0340

Dear Mr. Shah:

The Food and Drug Administration (FDA) has completed its evaluation of your Application for Special Termination of your permanent debarment. As you were informed by letter on December 10, 1997, FDA will not consider an application for special termination of debarment unless an applicant first clearly establishes that he or she provided *substantial assistance* in the investigations or prosecutions of certain offenses. This is a matter of law, and the Agency has no discretion whatsoever in this regard. Without a clear showing of substantial assistance, the Agency cannot terminate a debarment. An applicant must not merely assert that he or she provided substantial assistance, but must present independent evidence of substantial assistance.

In your original application (Exhibit 1) and supplements to the application, you discussed the basis for your claim of having provided substantial assistance to the government, and enclosed letters from Gary Tunkavige and Thomas Holland.<sup>1</sup> Mr. Tunkavige states that "information provided by Mr. Shah, combined with information developed from other sources, contributed to the evidence of misconduct on the part of individuals associated with Par Pharmaceutical, Inc." (Exhibit 2 at 2). Mr. Holland states that "Mr. Shah took the initiative in contacting the authorities and continued to cooperate in the investigation" (Exhibit 3 at 1). Mr. Tunkavige's dealings with you predate the prosecution of Par and individuals from Par. Mr. Holland confirmed by telephone that he dealt with you solely before any indictments were issued, and that he was not involved in your prosecution.

On May 5, 1993, you were convicted by jury trial<sup>2</sup> of two Federal felonies: conspiracy to commit an offense against the United States and aiding and abetting false statements to a Federal agency (Exhibit 4). FDA contacted the Department of Justice (DoJ) to obtain additional information about your convictions. Lawrence McDade, Deputy Director of the Office of Consumer

<sup>1</sup> Mr. Tunkavige was a Consumer Safety Officer with the FDA, and served as the Lead Investigator for an inspection of your former employer, Par Pharmaceutical, Inc. (Exhibit 2 at 1). Mr. Holland is a special agent in the Office of the Inspector General, U.S. Department of Health and Human Services (Exhibit 3 at 1).

<sup>2</sup> In FDA's experience, defendants who provide substantial assistance to the government are typically convicted under plea agreements, so as not to expend government resources on a matter in which guilt is uncontested.

Exhibit : 4

Docket No. 93N-0340

about your convictions. Lawrence McDade, Deputy Director of the Office of Consumer Litigation at DoJ, informed by Chris Mead and Ray Bonner, the former Assistant United States Attorneys (AUSA) who prosecuted your case, notified FDA by letter that although you initially provided some truthful information about illegal Par activities, you also provided false information to DoJ and were involved in a scheme to extort funds from Par in return for not providing certain information to DoJ (see Exhibit 5).

You state further in your application that you were "the victim of [a] government cover-up with FDA," and that your attorney was incompetent to represent you (Exhibit 1 at 1). The district court and the Fourth Circuit Court of Appeals fully considered and dismissed as not relevant the facts underlying the claim that you were a victim of a government cover-up.<sup>3</sup> Similarly, your claims about ineffective counsel were previously addressed.<sup>4</sup> Neither claim substantiates your assertion that you provided substantial assistance to the government.

The above information demonstrates that you indeed provided some assistance to the government, but were not completely truthful in your disclosures and did not fully cooperate with the government. To provide assistance to the government, an informant's information, including responses to questions, need to be truthful.<sup>5</sup> Although you provided some truthful information to

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<sup>3</sup> You submitted as part of your application a letter you wrote to the Office of Professional Responsibility (OPR) at DoJ in which you claim that the U.S. Attorney's Office violated the Proffer made between you and that office (Exhibit 6 at 1). You note, however, that the U.S. Attorney's Office told you that you had "breached such agreement and the government was not precluded from using the information that [you] had provided" (Exhibit 6 at 2). As noted in OPR's response to your letter (Exhibit 7 at 1), the Fourth Circuit Court of Appeals held that your claims of assistance to the government were irrelevant to the jury's finding of your guilt:

Shah desired to enter evidence that he voluntarily came forth with the evidence that led to this and other prosecutions and that the FDA "appreciated" his help. While these contentions might have been true, they were wholly irrelevant to Shah's guilt. Because they were irrelevant, they were properly excluded. (Exhibit 8 at 2).

Moreover, the Proffer you signed states that you were not entitled to immunity from prosecution (Exhibit 9). In the course of the general prosecution of Par and Par employees, the government discovered that you had not disclosed all of your own illegal actions while a Par employee and the government prosecuted you for these actions. This prosecution, therefore, was not a violation of the terms of the Proffer and there appears to have been no "cover-up."

<sup>4</sup> You claim that OPR "determined that in fact my trial attorney was at fault and incompetent to represent me during the trial" (Exhibit 1 at 2), but you did not include a copy of the response you received from OPR. In fact, OPR simply informed you that "[s]uch claims are not appropriate for the Department of Justice's consideration" and recommended that you contact the state bar or the court clerk for further assistance. (Exhibit 7 at 1).

<sup>5</sup> The Federal Food, Drug, and Cosmetic Act does not define the term "substantial assistance." However, the phrase is used in the context of the sentencing guidelines. See, e.g., *United States v. Avellino*, 136 F.3d 249 (2d Cir. 1998) (discussing the government's discretion to evaluate a defendant's assistance and the government's right to terminate a cooperative agreement where the defendant lies to the government).

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FDA and to DoJ, the quality of your assistance was marred by untruthfulness. Therefore, the Agency does not find that you provided substantial assistance to the government. First, you did not provide complete or wholly truthful information to the government. Second, you did not take responsibility for your own crimes, which meant the government had to expend significant government resources to prosecute you.

The Agency finds that you did not provide substantial assistance in the investigations or prosecutions of generic drug offenses. Your application for special termination of debarment is therefore denied.

Sincerely yours,



for Gary J. Dykstra  
Acting Associate Commissioner  
for Regulatory Affairs

DR. BEN SWATZ

(404) 253-1171

Exhibits

Mr. Jenis Baker  
Assoc.

(301) 827-3101

Dear Mr Ash:

This is a final debarment order. Therefore, I submitted appeal to the dist. of Columbia Circuit as per rule. They also denied my appeal.

Thank you

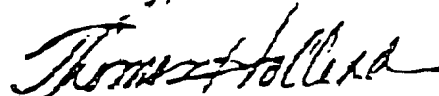
Satish Shah.

February 20, 1998

**To Whom It May Concern:**

I am a Special Agent in the Office of Inspector General, U.S. Department of Health and Human Services. In about 1989, I had occasion to interview Mr. Satish Shah. Mr. Shah, a former employee of Par Pharmaceutical, came forward and provided information concerning wrongdoing by PAR officials in the form of the creation of false records and misrepresentations to the Food and Drug Administration. By coming forward, Mr. Shah made a significant contribution to the government's investigation of PAR. It should be noted that Mr. Shah took the initiative in contacting the authorities and continued to cooperate in the investigation.

Sincerely,



Thomas Holland

U.S. Department of Health and Human Services  
Office of Inspector General  
330 Independence Avenue SW, Rm. 5193  
Washington, D.C. 20201

Exhibit: 6B