

Research and Production Act of 1993, 15 U.S.C. 4301 *et seq.* ("the Act"), Specialty Metals Processing Corporation has filed written notifications simultaneously with the Attorney General and the Federal Trade Commission disclosing changes in its membership status. The notifications were filed for the purpose of extending the Act's provisions limiting the recovery of antitrust plaintiffs to actual damages under specified circumstances. Specifically, GE Aircraft Engines, Cincinnati, OH; Dynamet, Washington, PA; Allied Signal Engines, Phoenix, AZ; United Technologies Corporation—Pratt & Whitney Division, East Hartford, CT; Schultz Steel Company, South Gate, CA; and Titanium Metals Corporation, Henderson, NV have been added as parties to this venture. Also, Allegheny Ludlum Steel Corporation, Brackenridge, PA has been dropped as a party to this venture.

No other changes have been made in either the membership or planned activity of the group research project. Membership in this group research project remains open, and Specialty Metals Processing Corporation intends to file additional written notification disclosing all changes in membership.

On August 7, 1990, Specialty Metals Processing Corporation filed its original notification pursuant to Section 6(a) of the Act. The Department of Justice published a notice in the **Federal Register** pursuant to Section 6(b) of the Act on September 17, 1990 (55 FR 38173).

The last notification was filed with the Department on October 30, 1995. A notice was published in the **Federal Register** pursuant to Section 6(b) of the Act on April 10, 1996 (61 FR 15972).

Constance K. Robinson,

Director of Operations Antitrust Division.

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. 97-9]

John J. Cienki, M.D.; Revocation of Registration and Continuation of Registration With Restrictions

On January 28, 1997, the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration (DEA), issued an Order to Show Cause to John J. Cienki, M.D. (Respondent) of Colorado and Florida, notifying him of an opportunity to show cause as to why DEA should not revoke his DEA Certificates of Registration

BC1616929 and AC2221187, and deny any pending applications for renewal of such registrations, pursuant to 21 U.S.C. 823(f), 824(a)(1) and (a)(4).

By letter dated February 22, 1997, Respondent, through counsel, filed a timely request for a hearing, and following prehearing procedures, a hearing was held in Miami, Florida on September 24 and 25, 1997, before Administrative Law Judge Gail A. Randall. At the hearing, both parties called witnesses to testify and introduced documentary evidence. After the hearing, counsel for both parties submitted proposed findings of fact, conclusions of law and argument. On March 18, 1998, Judge Randall issued her Opinion and Recommended Ruling, recommending in effect that Respondent's DEA registration issued to him in Colorado be revoked and that his Florida DEA registration be continued with restrictions. On April 20, 1998, the Government filed Exceptions to the Opinion and Recommended Ruling of the Administrative Law Judge, and on April 30, 1998, Judge Randall transmitted the record of these proceedings to the Acting Deputy Administrator.

The Acting Deputy Administrator has considered the record in its entirety, and pursuant to 21 CFR 1316.67, hereby issues his final order based upon findings of fact and conclusions of law as hereinafter set forth. The Acting Deputy Administrator adopts, in full, the Opinion and Recommended Ruling of the Administrative Law Judge. His adoption is in no manner diminished by any recitation of facts, issues and conclusions herein, or of any failure to mention a matter of fact or law.

The Acting Deputy Administrator finds that Respondent is board certified in emergency medicine and toxicology. In the mid-1980's, Respondent was fulfilling a service commitment in rural Florida when he began abusing controlled substances. According to Respondent, he abused opiates such as "Demerol, Talwin, whatever I could get my hands on." His abuse occurred over a period of a few months and stopped temporarily when he moved to Miami, Florida in 1985. By 1988, his drug use had escalated to a point where he sought and received 28 days of inpatient treatment for his addiction. Thereafter, he signed up with the Physicians' Recovery Network (PRN) to monitor him for five years.

After completing his drug treatment in 1988, Respondent worked in Philadelphia, Pennsylvania until sometime in 1991. During that time, Respondent entered into a Physicians' Health Program contract and remained

involved with the program until he left Pennsylvania.

In 1991 Respondent moved to Mississippi and applied for a Mississippi Medical license. On the application, he answered "yes" to the question that asked whether he had a history of drug or alcohol abuse. As a result of his response, Respondent agreed to submit to certain conditions for licensure in a Consent Agreement including that he would submit to random, unannounced and witnessed urine and/or blood screens; that he would not administer, dispense or prescribe drugs to himself; that he would not treat himself or family members; and that he would comply with Federal and state laws governing the practice of medicine. Respondent testified that he believed that the Consent Agreement was the result of a non-disciplinary procedure and in fact the records from the Mississippi Board specifically state that the Consent Agreement was non-disciplinary. Respondent further testified that he did not believe that this medical license was restricted as a result of the Consent Agreement and the license itself did not indicate that it was restricted. Respondent remained in Mississippi until November 1993 when he moved to Denver, Colorado to do a toxicology fellowship.

On October 1, 1993, Respondent submitted a renewal application for DEA Certificate of Registration AC2221187, issued to him in Florida. Respondent answered "No" to the question on the application (hereinafter referred to as the liability question) which asked, "Has the applicant ever been convicted of a crime in connection with controlled substances under State or Federal law, or ever surrendered or had a Federal controlled substance registration revoked, suspended, restricted or denied, or ever had a State professional license or controlled substance registration revoked, suspended, denied, restricted or placed on probation?"

On January 12, 1995, Respondent submitted a renewal application for DEA Certificate of Registration BC1616929, issued to him in Pennsylvania, along with a request, which was subsequently granted, to transfer the registration to a Colorado address. Respondent answered "No" to the liability question on this application.

In June of 1994, Respondent relapsed and abused the non-controlled substance Stadol until March 5, 1995. Stadol has a potential for abuse due to its opiate-like effects and as a result, DEA has published a proposed rule

which would place the drug in Schedule IV. Respondent acquired Stadol for his own use by writing false prescriptions and by fraudulently telephoning prescriptions to local pharmacies. Consequently, Respondent was charged in Denver District Court with fraud and deceit to obtain a prescription drug, as well as criminal impersonation. In June of 1995, Respondent pled guilty to the misdemeanor charge of fraud and deceit to obtain a prescription drug and the criminal impersonation charge was dismissed.

As a result of his conviction, Respondent's Colorado medical license was placed on probation, and he ultimately did not renew it. In addition, Respondent surrendered his Mississippi medical license on September 18, 1995.

Respondent returned to Pennsylvania and on August 23, 1995, he entered into a contract with the Pennsylvania Physicians' Health Program. Thereafter, the Pennsylvania Medical Board placed Respondent's Pennsylvania medical license on probation for five years subject to several conditions, including monitoring by the Professional Health Monitoring Program.

On May 18, 1996, Respondent entered into another contract with Florida's PRN which remains in effect as long as Respondent practices medicine in the State of Florida. As part of this program, Respondent is subject to random urine screens, which have all been negative. He attends five to six Alcoholics Anonymous meetings per week, professional group meetings twice a week, and PRN meetings once a week. According to Respondent, he has not used any drugs improperly since March 5, 1995.

On June 30, 1997, the Florida Board of Medicine issued a final order suspending Respondent's medical license for 30 days, fining him \$1,500.00, and reprimanding him. Following the period of suspension, Respondent's medical license was placed on probation for five years subject to several restrictions.

A physician, who is the medical director of an addiction treatment program, testified that he examined Respondent in 1988 and diagnosed drug addiction. In his opinion, Respondent was in strong denial at that time regarding his addiction. The physician again examined Respondent on September 9, 1997, and determined that Respondent "met criteria for recovery, that he had treatment, he had for a substantial amount of time had complied with his PRN contract, was attending meetings." According to the physician, Respondent is no longer in

denial and is committed to his recovery. In the physician's opinion, Respondent has "a nine out of ten chance over the next five years" for continued successful recovery because of his PRN contract and his comprehensive support system.

On August 31, 1996, Respondent's DEA Certificate of Registration AC2221187, issued to him in Florida, expired by its own terms. He submitted a renewal application for that registration on September 24, 1996, and answered "Yes" to the liability question. In explaining his answer, Respondent stated that "when I received my Mississippi license, a Consent agreement was placed on my license * * * I did not previously report this as I did not interpret this to be a suspension or restriction on my license." This renewal application was treated as timely, and was accepted for filing by DEA.

Before reaching the issue of whether Respondent's registrations should be revoked, Judge Randall addressed whether there is anything to revoke since Respondent filed his renewal applications after the expiration date noted on the Certificates of Registration. DEA regulations do not specify a deadline for filing renewal applications, however DEA accepts renewal applications up to seven months following the expiration of a registration. If no renewal application is received within seven months following the expiration date, the registration number is retired or purged from the registration system. According to the Acting Chief of DEA's Registration and Program Support Section:

The DEA considers that the expiration date of a person's registration represents expiration of their authority to handle controlled substances. However, this event does not represent expiration of that person's ability to become registered under that same registration number, if a proper renewal application is subsequently filed. By accepting Dr. Cienki's renewal application, DEA considers his registration number, AC2221187, as reactivated and capable of renewal or denial when administrative proceedings are resolved.

Since a DEA registration is not retired or purged from the registration system until seven months after its expiration, the Acting Chief explains that the "process allows what would have been an 'expired' *registration number*, to remain susceptible to renewal for approximately seven months."

Judge Randall then conducted an analysis of Administrative Procedure Act (APA) rulemaking requirements to determine whether DEA is authorized to renew expired registrations without

subjecting the practice to notice and comment. As Judge Randall noted, "[a]ny agency action must be properly implemented to be enforced against the regulated public. Therefore, this DEA practice cannot be applied to the Certificate of Registration at issue implementation through notice and comment was required."

The Acting Deputy Administrator agrees with Judge Randall's conclusion that this practice did not require notice and comment since it is not a legislative rule. DEA's practice has no negative implications for the regulated public since it gives a registrant a second chance to submit a renewal application rather than a new application for registration. Instead, as Judge Randall finds, "[t]he DEA's practice may be best categorized as both an agency rule of practice and procedure, and as an interpretative rule," both of which do not require notice and comment before being implemented. The practice can be considered an agency rule of practice and procedure because "[b]y following its practice, the agency is able to process a large volume of applications. This process does not put a stamp of approval or disapproval on the conduct of registrants." The practice can also be considered an interpretative rule by interpreting and supplementing the Controlled Substances Act and existing DEA regulations which do not specifically address a deadline for filing a renewal application. Accordingly, Judge Bittner concluded, and the Acting Deputy Administrator agrees, that since DEA's practice of accepting a renewal application after the expiration date of the registration did not require notice and comment rulemaking, there are valid pending renewal applications.

The Acting Deputy Administrator notes that the status of Respondent's registration pending the resolution of these proceedings is not at issue since Respondent did not contend that he was authorized to handle controlled substances nor were there any allegations that Respondent handled controlled substances without being properly authorized. But, as Judge Randall notes, "it appears to be the Government's position that a registrant loses his ability to handle controlled substances as soon as his registration expires." In his affidavit, the Acting Chief of DEA's Registration and Support Section states that "[t]he DEA considers that the expiration date of a person's registration represents expiration of their authority to handle controlled substances." In addition, an internal DEA manual indicates that "[a] registration is legally invalid on the day after it expires * * *." The Government

in its exceptions affirms that this is the Government's position.

However, some of the Government's arguments seem to support an interpretation that once DEA accepts a renewal application for filing, the registration remains valid pending the outcome of the proceedings. In fact, Government counsel in its Memorandum filed on December 1, 1997, states that, "[c]onsistent with DEA administrative case law precedent, Respondent's DEA Certificates of Registration are being maintained on a day-to-day basis * * *." Additionally, in its Memorandum, Government counsel quoted a provision of the APA which states that,

When the licensee has made timely and sufficient application for a renewal or new license in accordance with agency rules, a license with reference to an activity of a continuing nature does not expire until the application has been finally determined by the agency. 5 U.S.C. 558(c).

The Government then asserted that, "[i]n this matter, by its acceptance for processing, DEA in effect determined that the application was timely and sufficient." Therefore, it appears that the Government is contending that because Respondent's renewal application was considered timely, the registration does not expire until the application is either granted or denied.

Consequently, the Acting Deputy Administrator finds that it is unclear what the Government's position is as to the status of a registration pending final disposition when the renewal application is filed after the expiration date. But, the Acting Deputy Administrator finds that it is unnecessary to resolve the issue here because the status of Respondent's registrations following execution of his renewal applications is not at issue in this proceeding. However, the Government is directed to ensure that whatever position it takes, with respect to the validity of a DEA registration if a renewal application is accepted for filing after the expiration date, is consistent with the APA and implemented in accordance with the APA's provisions.

Since there are valid pending renewal applications, the question now becomes whether there registrations should be revoked. The Deputy Administrator may revoke or suspend a DEA Certificate of Registration under 21 U.S.C. 824(c), upon a finding that the registrant:

- (1) Has materially falsified any application filed pursuant to or required by this subchapter or subchapter II of this chapter;
- (2) Has been convicted of a felony under this subchapter or subchapter II

of this chapter or any other law of the United States, or of any State relating to any substance defined in this subchapter as a controlled substance;

(3) Has had his State license or registration suspended, revoked, or denied by competent State authority and is no longer authorized by State law to engage in the manufacturing, distribution, or dispensing of controlled substances or has had the suspension, revocation, or denial of his registration recommended by competent State authority;

(4) Has committed such acts as would render his registration under section 823 of this title inconsistent with the public interest as determined under such section; or

(5) Has been excluded (or directed to be excluded) from participation in a program pursuant to section 1320a-7(a) of Title 42.

Pursuant to 21 U.S.C. 823(f), the following factors are considered by the Deputy Administrator in determining the public interest:

(1) The recommendation of the appropriate State licensing board or professional disciplinary authority.

(2) The applicant's experience in dispensing, or conducting research with respect to controlled substances.

(3) The applicant's conviction record under Federal or State laws relating to the manufacture, distribution, or dispensing of controlled substances.

(4) Compliance with applicable, State, Federal, or local laws relating to controlled substances.

(5) Such other conduct which may threaten the public health and safety. These factors are to be considered in the disjunctive, the Deputy Administrator may rely on any one or a combination of factors and may give each factor the weight he deems appropriate in determining whether a registration should be revoked or an application for registration be denied. See Henry J. Schwarz, Jr., M.D. Docket No. 88-42, 54 FR 16,422 (1989).

First, as to DEA Certificate of Registration BC1616929, issued to Respondent in Colorado, it is well-settled that DEA does not have the statutory authority under the Controlled Substances Act to issue or maintain a registration if the applicant or registrant is without state authority to handle controlled substances. See 21 U.S.C. 802(21), 823(f) and 824(a)(3). This prerequisite has been consistently upheld. See, e.g., Romeo J. Perez, M.D. 62 FR 16,193 (1997); Demetris A. Green, M.D., 61 FR 60,728 (1996); Dominick A. Ricci, M.D., 58 FR 51,104 (1993).

Respondent did not renew his Colorado medical license and therefore,

he is not currently authorized to handle controlled substances in the State of Colorado. It is reasonable to infer, and Respondent does not deny, that because he is not authorized to practice medicine in Colorado, he is also not authorized to handle controlled substances in that state. As a result, Respondent is not currently entitled to a DEA registration in Colorado. Consequently, the Acting Deputy Administrator finds that DEA Certificate of Registration BC1616929, must be revoked.

Next, the Acting Deputy Administrator considers whether grounds exist to revoke DEA Certificate of Registration AC2221187, issued to Respondent in Florida. Pursuant to 21 U.S.C. 824(a)(1), a registration may be revoked if the registrant has materially falsified an application for registration. DEA has previously held that in finding that there has been a material falsification of an application, it must be determined that the applicant knew or should have known that the response given to the liability question was false. See, Martha Hernandez, M.S. 62 FR 61,145 (1997); Herbert J. Robinson, M.D. 59 FR 6304 (1994).

On his renewal applications dated October 1, 1993, and January 12, 1995, Respondent answered "No" to the liability question which asks in part whether the applicant has "ever had a State professional license or controlled substance registration revoked, suspended, denied, restricted, or placed on probation." This answer was given despite the fact that Respondent obtained a medical license in the State of Mississippi pursuant to a Consent Agreement which prohibited him from self-prescribing controlled substances. Respondent argues that he did not believe that his license was restricted and that the records from the Medical Board indicated that the Consent Agreement was non-disciplinary. But, the Acting Deputy Administrator agrees with Judge Randall's conclusion that "[s]ince the Respondent had been prohibited from self-prescribing controlled substances per the terms of the Mississippi Consent Agreement in 1991, he 'knew or should have known' the appropriate response to the liability question was 'yes' at the time he prepared his October 1993 and January 1995 renewal applications."

Therefore, the Acting Deputy Administrator concludes that Respondent materially falsified these applications and as a result, grounds exist to revoke Respondent's registration. However, like Judge Randall, the Acting Deputy Administrator finds it relevant that

Respondent answered "Yes" to the liability question on his September 24, 1996 renewal application, following the surrender of his Mississippi medical license. As Judge Randall concludes, "[b]y so answering, the Respondent has demonstrated an awareness and a willingness to answer truthfully this liability question."

Finally, the Acting Deputy Administrator considers the factors set forth in 21 U.S.C. 823(f) to determine whether Respondent's continued registration would be inconsistent with the public interest pursuant to 21 U.S.C. 824(a)(4). Regarding factor one, on June 30, 1997, the Florida Board of Medicine issued a final order suspending Respondent's medical license for 30 days, fining him \$1,500.00, and reprimanding him. Following the period of suspension, Respondent's medical license was placed on probation for five years subject to several restrictions, including that he continue his recovery program under the supervision of the Florida PRN as long as he practices medicine in the State of Florida. Therefore, Respondent's Florida medical license is currently on probation.

As to factors two and four, Respondent's experience in dispensing controlled substances and his compliance with applicable laws related to controlled substances, it is undisputed that beginning in the mid-1980's, Respondent abused controlled substances. In 1988, he sought and received treatment for his addiction. While he suffered a relapse in 1994, he abused Stadol which is not a controlled substance. Thus, there is no evidence that Respondent abused or improperly dispensed controlled substances after 1988.

Regarding factor three, there is no evidence that Respondent has a conviction record under Federal or state laws relating to the manufacture, distribution, or dispensing of controlled substances. Respondent's conviction in 1995 related to his writing of false prescriptions for the non-controlled substance Stadol.

As to factor five, the Acting Deputy Administrator agrees with Judge Randall's concern regarding Respondent's abuse of Stadol and his authorizing of false prescriptions to obtain the drug. However, Respondents has not improperly used drugs since March 1995, and has been actively involved in recovery since that time. Respondent's contract with the Florida PRN requires random urine screens, and attendance at Alcoholics Anonymous and professional group meetings. According to the medical director of the

addiction treatment facility who testified at the hearing, Respondent's prognosis for continued recovery is excellent, and a relapse would not go unnoticed given his PRN contract and his comprehensive support system.

The Acting Deputy Administrator concludes that grounds exist to revoke Respondent's Florida DEA registration. Respondent materially falsified two renewal applications, and he has a history of substance abuse. However like Judge Randall, the Acting Deputy Administrator does not find that revocation is warranted in this case.

While Respondent did indeed materially falsify two renewal applications, he answered the liability question correctly on his September 1996 renewal application. This is significant since this application was filed before the Order to Show Cause was issued in this matter which alleged that Respondent materially falsified applications. Also there is no question that Respondent has a history of substance abuse. But as Judge Randall notes "although it has been only three years since the Respondent's last relapse, I find the Respondent's testimony concerning his commitment to sobriety credible." In addition, Respondent's medical license is on probation until June 30, 2002, and he must remain under contract with the Florida PRN as long as he practices in Florida. Therefore, the Acting Deputy Administrator agrees with Judge Randall that revocation would be "too severe a resolution in this case."

But, an unrestricted registration is not warranted given Respondent's history of substance abuse and his fraudulent prescribing to obtain Stadol for his own use. Subjecting Respondent's registration to some restrictions "will allow the Respondent to demonstrate that he can responsibly handle controlled substances in his medical practice, yet simultaneously protect the public by providing a mechanism for rapid detection of any improper activity related to controlled substances." See Michael J. Septer, D.O. 61 FR 53,762 (1996); Steven M. Garbner, M.D., 51 FR 12,576 (1986).

The Acting Deputy Administrator agrees with Judge Randall's recommendation that Respondent's renewal application be granted subject to the following restrictions for three years:

- (1) Respondent shall not prescribe or otherwise dispense controlled substances or Stadol for himself or his immediate family members.
- (2) Respondent shall not order, administer, prescribe, or otherwise dispense controlled substances or

Stadol except in the course of his employment in a medical clinic or hospital.

(3) Respondent shall maintain a log of his handling of controlled substances and Stadol. At a minimum, the log shall include the date that the controlled substance or Stadol is prescribed, administered or dispensed, the name of the patient, and the name, dosage and quantity of the substance prescribed, administered or dispensed. The log shall be signed by Respondent's supervisor verifying the accuracy of the log, and shall be sent on a quarterly basis to the Special Agent in Charge of the DEA Miami Field Division, or his designee.

(4) Respondent shall inform the Special Agent in Charge of the Miami Field Division, or his designee, of any action taken by any state regarding his medical license or his authorization to handle controlled substances. This notification must occur within 30 days of the state action.

Accordingly, the Acting Deputy Administrator of the Drug Enforcement Administration, pursuant to the authority vested in him by 21 U.S.C. 823 and 824, and 28 CFR 0.100(b) and 0.104, hereby orders that DEA Certificate of Registration BC1616929, previously issued to John J. Cienki, M.D., be, and it hereby is revoked. The Acting Deputy Administrator further orders that DEA Certificate of Registration AC2221187, issued to John J. Cienki, M.D., be renewed and continued, subject to the above described restrictions. This order is effective October 30, 1998.

Dated: September 24, 1998.

Donnie R. Marshall,

Acting Deputy Administrator.

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DEPARTMENT OF JUSTICE

Office of Justice Programs

Agency Information Collection Activities: Proposed Collection; Comment Request

ACTION: Notice of Information Collection Under Review; (Reinstatement, without change, of a previously approved collection for which approval has expired) Claim for Death Benefits.

The Department of Justice, Office of Justice Programs, Bureau of Justice Assistance, has submitted the following information collection request for review and clearance in accordance with the Paperwork Reduction Act of 1995. This proposed information