remains should contact Dr. Frank E. Wozniak, NAGPRA Coordinator, Southwestern Region, USDA Forest Service, 517 Gold Ave. SW, Albuquerque, NM 87102; telephone: (505) 842-3238, fax: (505) 842-3800, before March 25, 1999. Repatriation of the human remains to the Hopi Tribe and the Yavapai-Prescott Indian Tribe may begin after that date if no additional claimants come forward.

Dated: January 25, 1999.

Francis P. McManamon,

Departmental Consulting Archeologist, Manager, Archeology and Ethnography Program.

[FR Doc. 99–4470 Filed 2–22–99 ; 8:45 am]

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. 96–32]

Pettigrew Rexall Drugs; Revocation of Registration

On April 8, 1996, the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration (DEA), issued an Order to Show Cause to Pettigrew Rexall Drugs (Respondent) of Adamsville, Tennessee, notifying the pharmacy of an opportunity to show cause as to why DEA should not revoke its DEA Certificate of Registration, AP0406911, pursuant to 21 U.S.C. 824(a)(4), and deny any pending applications for registration pursuant to 21 U.S.C. 823(f), for reason that its continued registration would be inconsistent with the public interest.

By letter dated May 1, 1996, Respondent, through counsel, filed a request for a hearing and the matter was docketed by Administrative Law Judge Mary Ellen Bittner. In the midst of prehearing proceedings, Respondent filed a Motion to Dismiss arguing that this action is barred by the statute of limitations, estoppel, laches and the Double Jeopardy Clause of the Fifth Amendment. In addition, Respondent filed a Motion in Limine to Exclude Evidence based upon the hearsay nature of some of the evidence and that the evidence is barred by the statute of limitations. Judge Bittner denied both of these motions and a hearing was held in Memphis, Tennessee on March 4 and 5, 1997. At the hearing, both parties called witnesses to testify and introduced documentary evidence. After the hearing, both parties submitted proposed findings of fact, conclusions of law and argument. On July 9, 1998, Judge Bittner issued her Opinion and Recommended Ruling, Findings of Fact, Conclusions of Law and Decision, recommending that Respondent's DEA Certificate of Registration be revoked. On July 28, 1998, Respondent filed its Exceptions to the Opinion and Recommended Ruling, Findings of Fact, Conclusions of Law and Decision of the Administrative Law Judge. Thereafter, Judge Bittner transmitted the record of these proceedings to the then-Acting Deputy Administrator on August 13, 1998.

The 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 Deputy Administrator adopts the findings of fact and conclusions of law of the Administrative Law Judge and in part adopts the recommended decision. The Deputy Administrator's 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 Deputy Administrator finds that Respondent is a pharmacy located in Adamsville, Tennessee and is owned and operated by Jimmy Max Pettigrew, R.Ph. Respondent has been in operation since 1963.

During an unrelated investigation in 1993, state investigators examined Respondent's computerized records and noticed that some individuals appeared to be filling controlled substance prescriptions over extended periods of time. The investigators compared the computerized records with Respondent's prescription records and discovered that essentially all of the suspect prescriptions were oral rather than written. The investigators then took patient profiles from Respondent's computerized records to the doctors listed as the prescribing physicians and asked them to verify that they had authorized the oral prescriptions. The doctors compared the patient profiles from Respondent with their patient records and where there were discrepancies, the investigators obtained affidavits from the doctors indicating what prescriptions they had a record or recollection of authorizing.

As a result of the investigation, a Grand Jury for the United States District Court for the Western District of Tennessee, Eastern Division returned a 294-count indictment against Mr. Pettigrew on May 16, 1994, and the case was heard before a jury in March 1995. A number of the counts were dismissed following a defense motion at trial and the jury acquitted Mr. Pettigrew of the remaining counts.

Based upon a review of Respondent's patient profiles, the prescriptions found at Respondent, the doctors' affidavits, testimony of several of the doctors at the criminal proceeding, and Mr. Pettigrew's testimony at the hearing in this matter, the Deputy Administrator makes the following findings regarding the 14 customers whose prescriptions are at issue in this proceeding.

According to Respondent's records, between January 1, 1987 and September 11, 1991, it dispensed 2,150 dosage units of Tylenol No. 3 to Patient 1 that were orally prescribed by John N. Jenkins, M.D. In his affidavit, Dr. Jenkins stated that his patient file indicated prescriptions issued to Patient 1 during this time period for a total of 550 dosage units of Tylenol No. 3, which included refills. Thus, Respondent dispensed approximately 1,600 dosage units of Tylenol No. 3 to Patient 1 pursuant to purported oral prescriptions that were not documented in her physician's records.

Dr. Jenkins testified in the criminal trial while Respondent's patient profile indicates that he had authorized 43 dispensings of Tylenol No. 3 for Patient 1, the patient record only indicates that he authorized 14 of them. He acknowledge that it was possible that oral prescriptions were occasionally not recorded in his patient files, but that it was unlikely that there would be 29 prescriptions for one patient that he had authorized but not charted. But according to Mr. Pettigrew, he called Dr. Jenkins on three or four occasions and Dr. Jenkins gave Mr. Pettigrew permission to dispense Tylenol No. 3 to Patient 1 without calling for authorization each time, ''as long as she's taking it within reason.'' Nonetheless, Mr. Pettigrew indicated that he called Dr. Jenkins' office each and every time for authorization to dispense to this patient.

Respondent's records indicate that between November 17, 1986 and September 5, 1991, it dispensed 2,520 dosage units Ativan 1 mg. to Patient 2 pursuant to oral prescriptions authorizes by John W. Prather, M.D. In his affidavit, Dr. Pratcher stated, ''It has been my practice not to telephone prescriptions for Ativan for my patients. Any prescriptions for Ativan would have to be written by me.'' In addition, Dr. Prather stated that he had not seen Patient 2 since April 6, 1988. Patient 2's profile also indicates that on a number of occasions, Respondent dispensed more than five refills of a prescription and without one prescription, refilled it

five times for more than the amount authorized by the original prescription.

As to Patient 3, Respondent's records indicate that between January 1, 1987 and September 18, 1991, Respondent dispensed 3,830 dosage units of Tylenol No. 3 pursuant to prescriptions by Dr. Prather. In his affidavit Dr. Prather stated, ''It has been my practice not to telephone prescriptions for Tylenol #3 tablets. Prescriptions for Tylenol #3 are generally written by me.'' Three written prescriptions by Dr. Prather for Tylenol No. 3 for Patient 3 were found in Respondent's records accounting for 170 dosage units and leaving a 3,660 dosage unit discrepancy between Respondent's records and Dr. Prather's affidavit. In addition, there were three prescriptions for this patient found in Respondent's records which did not indicate any refills were authorized, but refills were dispensed.

At the criminal trial, Dr. Prather testified that Patient 3 has been his patient for approximately 8 to 10 years and was also his neighbor. Dr. Prather testified that if he did telephone in a prescription for Tylenol No. 3 for Patient 3, ''it would be no refills.'' However, Dr. Prather also identified a prescription he had written for Patient 3 for Tylenol No. 3 that his own office records did not reflect, and conceded that because Patient 3 is a friend and neighbor, not all of his dealings with her were recorded in his office records.

Regarding Patient 4, Respondent's records indicate that between January 1, 1990 and August 29, 1991, Respondent dispensed 1,480 dosage units of propoxyphene hydrochloride 65 mg. pursuant to oral prescriptions authorized by James King, M.D. However, Dr. King indicated in his affidavit that he had not seen Patient 4 since 1989 and that he did not authorize Respondent to fill or refill prescriptions for propoxyphene hydrochloride during the time period at issue.

Respondent's records indicate that between January 1, 1984 and August 22, 1991, Respondent dispensed 1,680 dosage units of Talwin Nx 50 mg. to Patient 5 pursuant to oral prescriptions authorized by Dr. King. But Dr. King stated in his affidavit that although Patient 5 was his patient, he has never prescribed any pain medication for her and specifically did not authorize Respondent to fill or refill any prescription for Talwin for Patient 5.

As to Patient 6, Respondent's records indicate that between January 1, 1987 and August 28, 1991, Respondent dispensed 4,365 dosage units of Fiorinal No. 3 pursuant to oral prescriptions authorized by Michael Brueggeman, M.D. Dr. Brueggeman stated in his affidavit that he has not seen Patient 6 since November 16, 1984, that he did not authorize Respondent to dispense her Fiorinal No. 3, and that he had no record of ever prescribing that medication to her.

At the criminal trial, Dr. Brueggeman testified that he had no recollection of Patient 6, but that his records showed that he prescribed her Tylenol No. 3 in 1984 for arm pain. He further testified that he had no record or recollection of ever authorizing any prescriptions for Fiorinal No. 3 for Patient 6 between May 16, 1989 and August 20, 1991. Dr. Brueggeman also testified that generally, when a patient calls his office for a prescription, his nurse collects the necessary information, obtains authorization from him, telephones the pharmacy to order the drug, and then notes the prescription on the patient chart. He stated however that it is not his policy to renew medications if he has not seen a patient within one year. Dr. Brueggeman acknowledged that on occasion, he may be asked to authorize a prescription over the telephone, and also that there was a slight possibility that his nurse could have failed to chart a particular prescription. But Dr. Brueggeman stated that it would be ''very unlikely'' that the nurse failed to chart all of the prescriptions attributed to him on Respondent's patient profile for Patient 6. However during cross-examination, Dr. Brueggeman was shown a written prescription for Fiorinal No. 3 that he issued to Patient 6 in 1984 that was not reflected in her patient chart.

Regarding Patient 7, Respondent's records indicate that between January 1, 1987 and September 18, 1991, Respondent dispensed 575 dosage units of Tylenol No. 3 pursuant to oral prescriptions authorized by Thomas West, M.D. In his affidavit, Dr. West indicated that although Patient 7 had been a patient since at least 1979, he had no record of prescribing Tylenol No. 3 to Patient 7. Dr. West further stated that although it was possible that he orally prescribed Tylenol No. 3 for Patient 7, it was his practice to prescribe about 12 dosage units at a time and he would rarely authorize refills of such a prescription.

At the criminal trial, Dr. West essentially reiterated the statements in his affidavit. He further testified that Patient 7 was also a personal friend of his. Dr. West would not go as far as to say that he did not prescribe the medication in question because he did not ''have a particular recollection of any one event'' and he did not record every controlled substance he prescribed, but he was adamant that he would not prescribe refills for Tylenol No. 3 or any other narcotic.

As to Patient 8, Respondent's patient profile indicates that between October 1, 1986 and September 12, 1991, Respondent dispensed 280 dosage units of Vicodin pursuant to prescriptions authorized by Yolanda Tai, M.D. Respondent's records contain one written prescription that Dr. Tai issued for 40 dosage units of Vicodin with no refills, dated March 26 but not indicating the year, and four oral prescriptions purportedly authorized by Dr. Tai. In her affidavit, Dr. Tai stated that the only time she authorized Respondent to dispense Vicodin to Patient 8 was by written prescription on March 26, 1991, and that she was not in town on the dates that Respondent's records indicate that she authorized the other prescriptions for Patient 8. Thus there is a 240 dosage unit discrepancy between Respondent's records and Dr. Tai's affidavit.

Dr. Becker testified at the criminal trial that she participated in Patient 8's care as an intern, and that she wrote him a prescription for 40 Vicodin with no refills upon his release from the hospital following surgery. She testified that she did not authorize any of the prescriptions listed on Respondent's patient profile for Patient 8 and that she never authorizes prescriptions over the telephone because she feels that a patient in pain needs to be seen by the doctor. Dr. Becker did acknowledge that the notes of Patient 8's surgeon in charge indicated that as of June 3, 1991, Patient 8 was still taking Vicodin twice a day for pain.

Respondent's records also indicate that between October 1, 1986 and September 12, 1991, Respondent dispensed 3,300 dosage units of chlordiazepoxide 25 mg. to Patient 8 pursuant to oral prescriptions authorized by Joseph Rowland, M.D. However, in his affidavit Dr. Rowland stated that he last saw Patient 8 in 1974 and that he did not authorize any of the prescriptions listed in Respondent's records for Patient 8. At the criminal trial, Dr. Rowland testified consistent with his affidavit and also stated that he would not prescribe any kind of medication to a patient that he had not seen in 15 years. He admitted that he had no independent recollection of a particular prescription for Patient 8, however he would likely remember a patient if he was prescribing the amount of medication shown on Respondent's patient profile for Patient 8.

Respondent's records indicate that between January 1, 1987 and August 28, 1991, Respondent dispensed 1,170 dosage units of Valium 5 mg. to Patient

9 pursuant to oral prescriptions authorized by Robert Mandle, M.D. But in his affidavit, Dr. Mandle stated that although Patient 9 had been his patient since 1976, he had never prescribed her Valium 5 mg. and did not authorize Respondent to dispense any Valium to her. At the criminal trial, Dr. Mandle testified that he had no records of prescribing Valium to Patient 9 since 1976. During cross-examination, Dr. Mandle was shown a patient history for Patient 9 written by his partner Dr. Jenkins in 1986, which indicated that Patient 9 was a ''regular patient of Dr. Mandle'' and that she ''takes thyroid and Valium.'' In addition, Dr. Mandle was shown a 1986 psychiatric consultation written by another physician which stated, ''[Patient 9] is taking Valium, 5 milligrams, as needed but never frequently. This [is] prescribed by Dr. Mandle.'' However, Dr. Mandle explained at the trial that when a doctor takes a patient history, he generally obtains such information from the patient and does not verify its accuracy.

As to Patient 10, Respondent's records indicate that between January 1, 1987 and October 2, 1991, Respondent dispensed 7,715 dosage units of Darvocet-N pursuant to oral prescriptions authorized by Harry Peeler, M.D. Dr. Peeler stated in his affidavit that he last prescribed Darvocet for Patient 10 on September 24, 1985, and that he did not authorize any of the Darvocet precriptions listed in Respondent's records during the time period at issue.

Regarding Patient 11, Respondent's records indicate that between January 1, 1986 and September 5, 1991, Respondent dispensed 1,020 dosage units of generic phentermine 30 mg. or Fastin pursuant to oral prescriptions authorized by Dr. Peeler. However, Dr. Peeler stated in his affidavit that he neither recalled nor had any record of ever having seen Patient 11 and that he did not authorize Respondent to fill any prescriptions for Fastin or phentermine 30 mg. for her.

Respondent's records indicate that between January 1, 1987 and February 5, 1991, it dispensed 570 dosage units of phentermine 30 mg. to Patient 12 pursuant to oral prescriptions authorized by Dr. Peeler. Dr. Peeler stated in his affidavit that he had not seen this patient since April 2, 1985, that he did not authorize Respondent to fill any prescriptions for phentermine for her, and that it was his practice to not authorize refills on weight control medications.

Regarding Patient 13, Respondent's records indicate that between December 19, 1987 and April 12, 1991, Respondent dispensed 1,095 dosage units of Tylenol No. 3 pursuant to oral prescriptions authorized by J.L. Freeman, M.D. In his affidavit, Dr. Freeman stated that he did not authorize any Tylenol No. 3 for his patient during the relevant time period and that he moved his practice to another city in Tennessee in January 1990.

Finally, as to Patient 14, Respondent's records indicate that between January 1, 1987 and September 18, 1991, it dispensed 930 dosage units of Fastin pursuant to oral prescriptions authorized by James Thomas, M.D. However, Dr. Thomas stated in his affidavit that he had no record of having seen this patient in the previous five years, that it was his practice not to prescribe more than a one month supply of diet pills without seeing the patient, and that he did not authorize Respondent to fill any prescriptions for Fastin for this patient during the time period at issue.

In addition during the course of reviewing Respondent's records, the investigators noted that a number of the oral prescriptions did not contain all of the required information including the date, the physician's DEA registration number and address, and/or the patient's address. Also, Respondent's records indicated that on occasion it refilled prescriptions more than five times, it dispensed refills of controlled substances in an amount exceeding that of the original prescription, and it dispensed refills even though the original prescription did not authorize them. Further on a number of prescriptions, there were no initials of the pharmacist who received the oral prescription on the written memorialization as required by the State of Tennessee.

A number of the doctors who testified at the criminal trial, as well as the state investigator, noted that physicians are not required to keep a record of their prescribing of controlled substances. An expert physician who testified on behalf of Respondent at the hearing in this matter stated that the general practice in Western Tennessee regarding noting prescriptions in patient records has not been very good until recently. The expert testified that ''[t]he problem is that if you're at the hospital and someone calls and needs medication, you may call the druggist and say, hey, refill the medication. And that never gets—that rarely gets into the chart. Or you can be in your car calling it in. Or you can tell your staff to call it in, and they may not put it down.'' The state investigator testified at the hearing that a doctor may be out of the office when authorizing an agent or employee to telephone a prescription for a patient to a pharmacy, and those prescriptions may not necessarily be recorded in the patient's chart. But the investigator noted that it is not common for doctors to not record prescribed medications since ''it's a good medical practice,'' to keep accurate patient records.

Respondent's expert also testified that he reviewed Respondent's patient profiles and the patient records of 16 patients at issue in the criminal proceeding and that in his opinion, the patients had legitimate medical needs for the controlled substances dispensed by Respondent, and there was nothing in these records that would cause him to become concerned about either the dosage or the frequency of these patients' prescriptions for controlled substances. Respondent also introduced into evidence the extensive medical records for some of these patients.

A relief pharmacist from Respondent testified that she never dispensed medications at Respondent without proper authorization, nor did Mr. Pettigrew ever instruct her to do so. She further testified that she had no knowledge of Mr. Pettigrew ever dispensing controlled substances without a physician's authorization. This pharmacist suggested that the reason that the physicians denied authorizing certain prescriptions could be that a nurse in the doctor's office actually took the call. The pharmacist estimated that 80% of the calls authorizing oral prescriptions were made by personnel other than the authorizing physician. In addition, the pharmacist suggested that the doctor who actually authorized a particular prescription may not have been accurately listed on Respondent's patient profiles because the computer system in use at that time would automatically bring up the name of the last physician who prescribed for that patient. If the doctor's name was not manually changed, which was cumbersome when the pharmacy was busy, the previous doctor's name would remain as the prescribing physician.

In 1996, an individual who is an attorney and a pharmacist was hired by Respondent to conduct an inspection of the pharmacy. The individual testified at the hearing in this matter that Respondent appeared to be in compliance with all relevant state and Federal requirements. Specifically, the individual testified that Respondent's prescription drug stock appeared to be up to date and the quantities of drugs on hand were normal. He looked at random samples of patient profiles and prescriptions and found that all of the

prescriptions contained the required information. Additionally, he randomly selected various prescriptions and verified with the prescribing physicians that the prescriptions were authorized as indicated.

The individual further testified that he saw no correlation between unauthorized refills that occurred five to ten years ago, and the public interest as of the date of the hearing. According to the individual, Respondent is located in a very small town which is a medically underserved area, and because there are only two pharmacies in the area, it is his opinion that it is in the public's interest for Respondent to remain in business.

The part owner of the other pharmacy in town, who is also a physician, testified at the hearing. In his opinion, even if it is true that Respondent dispensed controlled substances without a physician's authorization, it would not be in the public interest to close Respondent because two pharmacies are necessary to serve this medically underserved area. According to this physician, as well as Mr. Pettigrew, it would be very difficult for Mr. Pettigrew to sell Respondent because a large number of its customers participate in the state medical assistance program which does not pay very much to pharmacies for prescriptions.

This individual also testified that on approximately 10 or 12 occasions, Respondent failed to obtain his authorization before refilling some of his patients' prescriptions. But, he also testified that he still believed it would be in the public interest for Respondent to retain its DEA registration since he would have authorized these prescriptions had he been consulted. However, he did express concern about the possible side effects his patients might suffer and about the risk that they might become addicted to the controlled substances that Respondent dispensed to them without authorization.

At the hearing in this matter, Mr. Pettigrew indicated that he knows the physicians at issue personally. He denied dispensing any controlled substances without a physician's authorization, but testified that he has nonetheless instituted new procedures at Respondent. He testified that now when a doctor's office telephones in a prescription, the pharmacist immediately writes down all of the required information on a prescription pad. If a patient brings in an expired prescription, the pharmacist telephones the doctor and requests authorization, which is then logged into Respondent's records as a new prescription. In addition, oral prescriptions are now initialed twice, once by the pharmacist who receives the authorization and again by the dispensing pharmacist. Further, Respondent has a new computer system which provides more details about a prescription than the system used in 1987–1991.

Mr. Pettigrew noted at the hearing that there have been no allegations of any wrongdoing at Respondent since 1991. According to Mr. Pettigrew the state investigators conduct a random inspection about once a year. Mr. Pettigrew further testified that he has instituted any changes suggested by the state investigators and that he is willing to do whatever is necessary to continue in compliance.

Pursuant to 21 U.S.C. 823(f) and 824(a)(4), the Deputy Administrator may revoke a DEA Certificate of Registration and deny any application for such registration, if he determines that the continued registration would be inconsistent with the public interest. Section 823(f) requires that the following factors be considered:

(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 or 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., 54 FR 16,422 (1989).

Regarding factor one, there is no evidence that the Tennessee Board of Pharmacy has taken any action against Respondent or Mr. Pettigrew. However, as Judge Bittner stated, ''inasmuch as state licensure is a necessary but not sufficient condition for DEA registration, * * * this factor is not dispositive.''

As to factors two and four, Respondent's experience in handling controlled substances and its compliance with applicable laws relating to controlled substances, there is considerable evidence in the record. The Government alleged that between 1987 and 1991 Respondent dispensed approximately 35,000 dosage units of controlled substances without a physician's authorization. Some of the physicians merely stated in their affidavits that their records did not reflect authorization for the oral prescriptions at issue. However, many of the physicians stated unequivocally that not only did their records not reflect authorization for oral prescriptions, but also that they did not orally prescribe the medication at issue; that they did not prescribe that specific medication for that patient; that the patients were not under their care during the relevant time period, and in fact had not been seen by the physician in years; or that they were not even their patients. The Deputy Administrator recognizes that neither Federal or state law requires physicians to keep records of their controlled substance prescriptions. Nevertheless the Deputy Administrator agrees with Judge Bittner that ''[t]he sheer quantity of 'prescriptions' Respondent filled and the number of physicians who stated that they had not authorized them suggests that practitioners' failure to maintain accurate records does not account for all of the dispensings at issue.''

Mr. Pettigrew contended that he contacted the physicians' offices to receive authorization for every controlled substance prescription. But, Judge Bittner did not find Mr. Pettigrew's contention credible, stating that ''Mr. Pettigrew did not favorably impress me as a witness; he did not appear candid or forthright and his testimony appeared to be tailored to Respondent's defense in this proceeding.''

The Deputy Administrator finds it hard to believe that all of the oral prescriptions at issue were authorized but not noted in the physicians' patient charts when other instances of prescribing were specifically noted in the charts. In addition, according to Respondent the physicians' patient charts did not reflect the prescriptions at issue, yet during the independent inspection of Respondent conducted in 1996, the physicians were able to verify that they authorized oral prescriptions found in Respondent's records. Consequently, the Deputy Administrator agrees with Judge Bittner that while some prescriptions may have been orally authorized by a practitioner or his agent, most were not. Respondent therefore dispensed controlled substances on numerous occasions without a physician's authorization in violation of 21 U.S.C. 829 and 21 C.F.R. 1306.21.

Respondent also presented evidence that the patients had medical needs for

the controlled substances dispensed to them. While this appears to be true, the Deputy Administrator concludes that this does not justify Respondent's dispensing of controlled substances to them without a physician's authorization. The law specifically states that ''no controlled substance in Schedule III or IV, . . . may be dispensed without a written or oral prescription. . . .'' See 21 U.S.C. 829(b). Controlled substances in Schedules III and IV may not be dispensed without a physician's authorization regardless of whether a pharmacist believes that there is a legitimate medical need for the drug.

Additionally, Respondent failed to properly reduce to writing oral prescriptions for Schedule III and IV controlled substances as required by 21 CFR 1306.05. A number of the prescriptions in evidence failed to include a date, the physician's DEA registration number, the patient's address, and/or the physician's address. Also, prescriptions were refilled more times than authorized, in amounts exceeding what was originally prescribed, and/or after the original prescription expired in violation of 21 U.S.C. 829 and 21 CFR 1306.22. Further, Respondent violated the state requirement that the pharmacist who receives an oral prescription must initial the documentation of it.

However, the Deputy Administrator notes that the most recent of these violations occurred in 1991. Evidence in the record suggests that Respondent has properly dispensed controlled substances and been in compliance with controlled substance laws since that time. An independent inspection conducted in 1996 found Respondent to be in compliance and apparently, yearly state inspections have not revealed any wrongdoing. Respondent has also installed a new computer system and instituted changes regarding its handling of oral prescriptions.

As to factor three, Mr. Pettigrew was acquitted of all criminal charges arising out of this investigation. It is undisputed that neither Respondent, Mr. Pettigrew or any other officer or agent of Respondent has been convicted of any controlled substance related offense.

The Deputy Administrator agrees with Judge Bittner that as to factor five, the record contains no evidence of other conduct that may threaten the public health or safety.

Judge Bittner concluded that Respondent's continued registration would not be in the public interest based upon its dispensing of ''enormous quantities'' of controlled substances without a physician's authorization; its violations of Federal and state laws relating to controlled substances; Mr. Pettigrew's failure to indicate any remorse for his actions; and that the changes to its operation do not address the particular problem. Judge Bittner concluded that in light of Mr. Pettigrew's denial of any wrongdoing, ''Respondent has not shown that the misconduct is not likely to recur and that Mr. Pettigrew is either unwilling or unable to carry out the responsibilities inherent in a DEA registration.'' Therefore, Judge Bittner recommended that Respondent's DEA registration be revoked.

Respondent filed exceptions to Judge Bittner's recommended decision and attached its earlier motions to dismiss and to exclude certain evidence. Respondent argued that all of the alleged misconduct occurred before September 1991, and thus this action and reliance on certain evidence is barred by 28 U.S.C. 2462 which establishes a five year statute of limitations for ''. . . an action, suit or proceeding for the enforcement of any civil fine, penalty, or forfeiture, pecuniary or otherwise. . . .'' The Deputy Administrator agrees with Judge Bittner that 28 U.S.C. 2462 is inapplicable in these proceedings. These proceedings are not punitive in nature, but instead are administrative and remedial. In looking to protect the public health and safety, it is clearly relevant to consider a registrant's past history in handling controlled substances to determine if it can be trusted to responsibly handle controlled substances in the future. Further, 21 U.S.C. 824(c) specifically states that proceedings such as these ''shall be independent of, and not in lieu of, criminal prosecutions or other proceedings under this subchapter or any other law of the United States.'' Therefore, these proceedings are clearly distinguished from civil proceedings.

Respondent also argues that the Government is estopped from bringing this action because it renewed Respondent's DEA registration after it had knowledge of the alleged misconduct and Respondent made changes to its procedures and purchased a new computer system based upon the suggestions of a state investigator. The Deputy Administrator agrees with Judge Bittner that estoppel is not available as a defense against the Government. Respondent further contends that this action is barred by the doctrine of laches. As Judge Bittner noted, as a general rule laches does not apply against the Government. DEA has consistently held that passage of time since the wrongdoing is not dispositive, however it is a factor to be considered. *See Hagura Pharmacy,* 62 FR 16,191 (1997); *John Porter Richards, D.O.,* 61 FR 13,878 (1996) and cases cited therein. In addition, Respondent argues that its due process rights were violated by the unreasonable delay in bringing this action. In support of its argument, Respondent cites several cases dealing with the violation of a party's due process rights based upon the delay in bringing a civil forfeiture action. This proceeding is clearly not analogous to a civil forfeiture action and therefore the Deputy Administrator does not find Respondent's argument persuasive. Respondent contends that Judge Bittner erred by failing to properly consider that the patients at issue had demonstrated medical needs for the medications dispensed by Respondent ''thereby making it likely that the drugs were, in fact prescribed by the physicians * * * and, therefore, did not and could not pose a threat to the public health and safety.'' In addition, Respondent argues that Judge Bittner erred by determining that most of the prescriptions were not authorized by a physician or his agent. The Deputy Administrator does not agree with Respondent's argument that since the individuals had medical needs for the drugs it is more likely that they were authorized by a physician. As discussed previously, the Deputy Administrator agrees with Judge Bittner's conclusion that most of the prescriptions at issue were not authorized by a physician or his agent. Of particular significance is that a number of the physicians had no record of even treating these patients for years prior to the relevant time period let along prescribing them controlled substances. Also, the one physician who did testify stated that there were 10 to 12 prescriptions found at Respondent that were attributed to him that he had not authorized.

Respondent further contends in its exceptions that in rendering her recommended decision in this matter, Judge Bittner erred in failing to consider that Respondent has been in compliance with Federal and state requirements since the alleged misconduct occurred; that it has taken corrective action regarding its operation; and that the loss of its DEA Certificate of Registration will result in Respondent's closure which would have a severe adverse impact on the community by eliminating one of two pharmacies serving a poor, medically underserved population. As discussed herein, the Deputy Administrator has considered

these facts in rendering his decision in this matter.

The Deputy Administrator concludes that the Government has made a prima facie case for revocation of Respondent's DEA registration. The Deputy Administrator is quite concerned about the nature and extent of the violations that occurred between 1987 and 1991. But of even greater concern is Respondent's failure to acknowledge or accept responsibility for any wrongdoing. That Respondent continues to argue that there is no danger to the public health and safety because the controlled substances were medically necessary indicates that Mr. Pettigrew still does not appreciate Respondent's role in the dispensing of controlled substances. Also of concern to the Deputy Administrator is Mr. Pettigrew's claims of ignorance of the requirements at the time of the events in question.

Therefore, the Deputy Administrator finds that revocation of Respondent's DEA registration is justified as inconsistent with the public interest. However, the Deputy Administrator also recognizes that Respondent is one of two pharmacies in a relatively poor, medically underserved community and it would most likely close if its DEA registration is revoked; that it has changed its procedures regarding oral prescriptions and its computer system; and that there is no evidence of any wrongdoing since the events at issue in this proceeding. As a result, the Deputy Administrator concludes that the public interest would be served by requiring Mr. Pettigrew to undergo training in order to fully appreciate the pharmacy's responsibilities as a DEA registrant and by subjecting Respondent to random unannounced inspections, while still being permitted to handle controlled substances.

Therefore the Deputy Administrator will stay the revocation of Respondent's DEA registration for six months during which time Respondent must present evidence to the Deputy Administrator of Mr. Pettigrew's completion of a training course regarding the proper handling of controlled substances and must submit to random unannounced inspections by DEA personnel without requiring an administrative inspection warrant. If alleged violations are discovered during these inspections, the Deputy Administrator will extend the stay pending proceedings to determine whether violations in fact occurred. If Respondent does not comply with these terms, or if it is determined that subsequent violations have occurred, an order will be issued lifting the stay and Respondent's DEA Certificate of Registration will be revoked. If Respondent does comply, the Deputy Administrator will issue a subsequent order indicating that the conditions have been met and that the DEA Certificate of Registration is reinstated and renewed without limitations.

Accordingly, the 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 AP0406911, issued to Pettigrew Rexall Drugs, be, and it hereby is, revoked, and any pending applications for renewal of such registration, be, and they hereby are, denied. It is further ordered that this order will be stayed for a period of six months from its effective date. If during the six month period, Respondent fails to comply with the above described conditions, the stay will be removed and Respondent's DEA Certificate of Registration will be revoked and any pending applications for renewal will be denied. This order is effective March 25, 1999.

Dated: February 16, 1999.

Donnie R. Marshall,

Deputy Administrator.

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DEPARTMENT OF JUSTICE

Immigration and Naturalization Service

Agency Information Collection Activities: Comment Request

ACTION: Notice of information collection under review; Guarantee of payment.

The Department of Justice, Immigration and Naturalization Service has submitted the following information collection request for review and clearance in accordance with the Paperwork Reduction Act of 1995. The proposed information collection is published to obtain comments from the public and affected agencies. Comments are encouraged and will be accepted for ''sixty days'' until April 26, 1999.

Written comments and suggestions from the public and affected agencies concerning the proposed collection of information should address one or more of the following four points:

(1) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(2) Evaluate the accuracy of the agencies estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

(3) Enhance the quality, utility, and clarity of the information to be collected; and

(4) Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses.

Overview of this information collection:

(1) *Type of Information Collection:* Reinstatement without change of previously approved collection

(2) *Title of the Form/Collection:* Guarantee of Payment.

(3) *Agency form number, if any, and the applicable component of the Department of Justice sponsoring the collection:* Form I–510. Office of Detention and Deportation, Immigration and Naturalization Service.

(4) *Affected public who will be asked or required to respond, as well as a brief abstract:* Primary: Business or other-for-profit. Section 253 of the Immigration and Nationality Act (Act) provides that the master or agent of a vessel or aircraft shall guarantee payment for expenses incurred for an alien crewman who arrived in the United Stats afflicted with any disease or illness mentioned in Section 255 of the Act.

(5) *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond:* 100 responses at 5 minutes (.083) per response.

(6) *An estimate of the total public burden (in hours) associated with the collection:* 8 annual burden hours.

If you have additional comments, suggestions, or need a copy of the proposed information collection instrument with instructions, or additional information, please contact Richard A. Sloan 202–514–3291, Director, Policy Directives and Instructions Branch, Immigration and Naturalization Service, U.S. Department of Justice, Room 5307, 425 I Street, NW., Washington, DC 20536. Additionally, comments and/or suggestions regarding the item(s) contained in this notice, especially regarding the estimated public burden and associated response time may also be directed to Mr. Richard A. Sloan.

If additional information is required contact: Mr. Robert B. Briggs, Clearance Officer, United States Department of Justice, Information Management and Security Staff, Justice Management