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UNITED STATES COURT OF APPEALS
FOR THE THIRD CIRCUIT

NO. 96-3099

EARL A. HUMPHREYS, M.D.,
Petitioner

v.

DRUG ENFORCEMENT ADMINISTRATION,
Respondent.

On Appeal from an Order of the Drug Enforcement Administration dated
January 23, 1996

(AH 16752)

Argued July 26, 1996

BEFORE: BECKER, STAPLETON, AND MICHEL, Circuit Judges.

(Opinion Filed September 17, 1996)

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OPINION OF THE COURT

MICHEL, Circuit Judge.

Earl A. Humphreys, M.D. ("Humphreys") appeals from an order of the Drug Enforcement Administration ("DEA"), dated January 23, 1996, in which the Deputy Administrator of the DEA ordered that Humphreys' DEA certificate of registration be revoked and any pending application for renewal of the registration be denied. Earl A. Humphreys, M.D.; Revocation of Registration, 61 Fed. Reg. 2840 (1996). Because the DEA abused its discretion in failing to consider Humphreys' privacy defense and, on the present record, arbitrarily revoked his registration, we vacate and remand.

BACKGROUND

Humphreys is a Pittsburgh doctor specializing in gastroenterology and internal medicine and who, prior to this proceeding, had practiced for over 35 years without any disciplinary actions being taken against him. On April 12, 1995, a Deputy Assistant Administrator of the DEA issued to Humphreys an Order to Show Cause why the DEA should not revoke Humphreys' certificate of registration under 21 U.S.C. § 824(a)(4) and deny any pending application under 21 U.S.C. § 823(f) as being inconsistent with the public interest. Specifically, the Order to Show Cause alleged that "from the early 1980s to mid-1993, [Humphreys] prescribed controlled substances to at least four individuals without a legitimate medical need and with knowledge that these individuals were not the ultimate recipients of the controlled substances."

The DEA's action was precipitated by Humphreys' personal and professional relationship with former Pennsylvania Supreme Court Justice Rolf Larson ("Larson") and the criminal investigation of Larson. Humphreys acted as Justice Larson's personal physician for approximately the past 20 years. In 1993, based on the findings and recommendations of a grand jury, Larson was charged with one count of conspiracy to commit "Acquisition or Obtaining of Possession of a Controlled Substance by Misrepresentation, Fraud, Forgery, Deception, or Subterfuge" and numerous other violations of law. Humphreys was named as an unindicted co-conspirator in the conspiracy count and received immunity in return for his testimony against Larson.

The criminal conspiracy charge against Larson, and DEA's regulatory investigation of Humphreys, stemmed from Larson's attempts to keep his mental health problems out of public sight. Beginning in the 1960's, Larson visited psychiatrists and psychologists for the treatment of clinical depression and anxiety. These doctors prescribed various tranquilizers and antidepressants, which Larson paid for out of his own pocket in order to preserve his privacy. Beginning in 1981, however, Larson revised his method of assuring his privacy: he asked Humphreys to prescribe various controlled drugs for Larson in the name of certain of Larson's employees

(secretaries and a law clerk). From the early 1980's to mid-1993, Humphreys wrote approximately 34 prescriptions for drugs in this manner, including prescriptions for Valium, Diazepam, Ativan, and Serax. It is undisputed that the individuals named on the prescriptions always gave the prescription drugs to Larson and did not take the medications themselves or resell them. It is also undisputed that Humphreys was aware of Larson's diagnosed condition, that he believed each medication he prescribed was for an appropriate medical purpose, and that he prescribed the substances in appropriate medical dosage amounts and at acceptable time intervals. Moreover, although Humphreys did not examine Larson each time he prescribed drugs, Humphreys did examine Larson before the first prescription and approximately every six months thereafter. Although Humphreys was aware that Larson was continuing to see other doctors, Humphreys was not aware of any other medications prescribed by Larson's other doctors and did not attempt to coordinate his prescriptions with those of these other doctors. Humphreys received no money for writing these prescriptions.

After receiving the Order to Show Cause, Humphreys and his attorney each filed a response to the Order. Humphreys' primary defense was that, by prescribing the medication in the names of Larson's close associates, he was attempting to protect Larson's privacy in a manner common and acceptable in standard medical practice for famous patients with mental conditions. Humphreys waived his right to a hearing, as he was recovering from a stroke.

On January 23, 1996, the Deputy Administrator entered his Final Order, based on the investigative record and Humphreys' written statement. The Deputy Administrator acknowledged that he could revoke Humphreys' registration only if continued registration would be inconsistent with the public interest pursuant to the five factors set forth in 21 U.S.C. § 823(f). The Deputy Administrator considered, discussed and relied upon each of the five factors except for factor three - Humphreys' conviction record under Federal or State laws relating to controlled substances, which, because he had none, was not a relevant factor - and, based upon these factors, determined that the public interest would be best served by revoking Humphreys' registration. The Deputy Administrator did not discuss, and apparently did not consider, Humphreys' privacy defense. Humphreys appealed, and this court granted a stay of the Order pending our disposition of this appeal. We have jurisdiction to hear this appeal under 21 U.S.C. § 877 (1994).

ANALYSIS

The Standard of Review

Agency decisions, such as the Deputy Administrator's Order, may be set aside only if arbitrary, capricious, an abuse of discretion or otherwise not in accordance with the law. 5 U.S.C. § 706(2)(A) (1994). "As

a reviewing court, we must accord proper deference to the DEA's expertise but must nonetheless make a 'searching and careful inquiry' of the record to determine whether the agency's decision was based on a consideration of the relevant factors and whether there was a clear error of judgment." *Trawick v. DEA*, 861 F.2d 72, 76 (4th Cir. 1988) (affirming revocation of registration) (citation omitted).

The Regulatory Framework

The Controlled Substances Act, as amended by the Dangerous Drug Diversion Control Act of 1984, Pub. L. No. 98-473, Title II, § 511, 98 Stat. 2073, requires that any person who dispenses controlled substances must first obtain a certificate of registration from the Attorney General. 21 U.S.C. §§ 822(a), 823(f) (1994). The Attorney General has delegated the authority to deny, revoke or suspend registrations to the Administrator of the DEA. 21 U.S.C. § 824 (1994); 28 C.F.R. § 0.100(b).

Prior to 1984, the DEA could revoke a registration for only three reasons: (1) falsification of an application; (2) felony conviction related to controlled substances; and (3) suspension, revocation or denial of a state license. In 1984, with the enactment of the Dangerous Drug Diversion Control Act, Congress added a fourth reason for which a registration could be revoked, namely, a finding that the physician had committed "such acts as would render his registration under section 823 of this title inconsistent with the public interest as determined under such section" 21 U.S.C. § 824(a) (1994). In determining whether registration would be inconsistent with the public interest, the DEA must consider the following factors:

- (1) The recommendation of the appropriate State licensing board or 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.

21 U.S.C. § 823(f) (1994). The five factors are independent, and the Deputy Administrator may revoke a registration based on one factor or a combination of several factors. *Henry J. Schwartz, M.D.*, 54 Fed. Reg.

16,422, 16,424 (1989).

The DEA bears the burden of proving that registration would not be in the public interest. See *Shatz v. United States Dep't of Justice*, 873 F.2d 1089, 1091 (8th Cir. 1989) ("We think the burden of persuasion and production on the issue whether registration would be in the public interest was correctly placed on the Administrator as an initial matter. Once the Administrator produced evidence of the state medical board's actions, the DEA investigation and the drug-related felony conviction, the burden of production only then shifted to Shatz to rebut this evidence.").

Applicability of the Statute to Humphreys and its Application

Humphreys raises two primary issues on appeal: whether 21 U.S.C. § 824(a) can apply to the facts of this case and, if so, whether the DEA properly applied the five public interest factors to his case and properly considered his privacy defense.

Initially, we may easily dispose of Humphreys' contention that 21 U.S.C. § 824(a) was never meant to apply to physicians in his circumstances. Citing *Trawick*, 861 F.2d at 76, Humphreys argues that the legislative history of the 1984 amendment indicates it was meant to apply only in egregious cases and was specifically directed to those physicians who prescribed controlled substances to addicts, who then could either use the drugs themselves or resell them in order to purchase different drugs, such as heroin. Humphreys argues that his actions did not fall within the category of egregious cases. Certainly, there is no allegation here of sales to addicts.

However, Humphreys, while relying on selected language in the *Trawick* opinion, has ignored not only the holding of the *Trawick* decision, but other language as well. In *Trawick*, a dentist was indicted on state felony drug charges, including conspiracy to distribute and distribution of cocaine, based on acts not related to his patients. 861 F.2d at 73-74. The dentist pled guilty only to misdemeanor possession of cocaine as part of a plea bargain. *Id.* at 74. Following his conviction, the DEA revoked his registration as being inconsistent with the public interest. *Id.* The Court of Appeals noted that the legislative history of the public interest standard was much as Humphreys now suggests, but concluded that the dentist there could not "avoid the plain statutory language of the amendment merely by showing that Congress, in enacting it was largely concerned with a situation different from the instant case." *Id.* at 76. Reasoning that a court must uphold any reasonable agency construction of a statute it is entrusted to enforce, the court concluded it was reasonable to interpret the statute to authorize revocation based on a misdemeanor drug conviction. *Id.* at 75-76. Likewise, here there is nothing unreasonable about the DEA's interpretation of the statute as authorizing revocation based on Humphreys' allegedly unlawful

and irregular prescription of controlled substances in the names of individuals other than his patient, Larson. As discussed below, however, the DEA's application of the statute to the precise situation facing Humphreys is so deficient as to be an abuse of discretion.

The Privacy Defense

In a combined discussion of factors two and four under 21 U.S.C. § 823(f), the two factors upon which the Deputy Administrator relied most heavily, the Deputy Administrator emphasized that Humphreys had engaged in a course of conduct during approximately a 12-year period that clearly violated federal drug prescribing regulations. Specifically, the Deputy Administrator concluded that Humphreys' conduct violated 21 C.F.R. § 1306.04(a), which provides that a prescription for a controlled substance "must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice." The Deputy Administrator concluded that these factors weighed in favor of revoking Humphreys' registration, as Humphreys' long practice of issuing prescriptions in the names of individuals unknown to him and not under his care would not meet this criterion.

The central deficiency in the Deputy Administrator's decision is his complete failure to discuss the one and only defense raised by Humphreys: that prescribing antidepressants and other such drugs for a famous patient in the name of another individual in order to preserve the privacy of the patient was, in fact, the "usual course" of medical practice in circumstances such as these and that, therefore, Humphreys did not violate the federal regulation. Humphreys squarely and intelligibly raised this defense before the Deputy Administrator, as before us.

Specifically, Humphreys, too ill to appear in person, wrote in a letter responding to the DEA Order to Show Cause that "[t]he psychiatrist and the neurologist at the trial for Justice Larson testified that they probably would have done the same thing and might have even used the same medications. They indicated that it is common practice, especially in psychiatric patients, to do this." Additionally, Humphreys' attorney wrote the following:

Separate and apart from Dr. Humphrey's [sic] opinion is the sworn testimony of Gerald

Sandson, M.D. given in the case of Commonwealth of Pennsylvania v. Rolf Larson at

#9313844, in which this psychiatrist completely concurred with the need for privacy in

the treatment of Justice Larson. . . . Testimony at trial showed that psychiatric patients

suffer a stigma in society, and that public figures bear even greater burden.

During the case of Commonwealth of Pennsylvania vs. [sic] Larson, it was established without contradiction, that on a daily basis, psychiatrists on the staffs of at least Allegheny General Hospital and the Western Psychiatric Institute prescribed drugs in names of people for whom the prescriptions were not intended because privacy was an essential part of the treatment of the patient. No prosecutions were ever brought for any of these doctors or hospitals.

Humphreys' attorney also asserted that the sworn testimony at the Larson trial also established that privacy was an essential part of Larson's treatment, that privacy was the reason the drugs were prescribed in the names of others, and that the manner and method of Larson's treatment were not inconsistent with generally accepted medical standards.

The Deputy Administrator apparently failed to consider any of this evidence, stating instead only that "the trial transcript from Justice Larson's trial was not a part of the investigative record, and the Respondent did not attach a copy of the referenced sections to his Reply." It is true that Humphreys failed to include the Larson trial transcripts he cited in the DEA record. Humphreys should have submitted these transcripts to the DEA for inclusion in the record. However, while the record did not contain these trial transcripts, the Deputy Administrator was clearly aware of the trial and referred specifically to Humphreys' testimony at a pre-trial hearing in the Larson case. Thus, the Deputy Administrator did have before him, and took notice of, Humphreys' sworn testimony, observing that

beginning in 1981 and continuing until 1993, [Humphreys] had issued prescriptions for Schedule IV controlled substances intended for Justice Larson's use, but he had issued the prescriptions in the name of third-parties. . . . [Humphreys] had never met these individuals, and they were not his patients. . . . [Humphreys] testified that he examined Justice Larson about every six months, but not necessarily prior to issuing each of the prescriptions. Rather, Justice Larson would telephone [Humphreys] and tell him what substances he wanted and in whose name to issue the prescription. . . . [Humphreys] was aware of Justice Larson's diagnosed condition . . . and that it was [his] belief that every medication he prescribed for Justice Larson was for a legitimate

medical purpose. [Humphreys] testified that he had prescribed the substances in legitimate medical dosage amounts and at appropriate time intervals. He states that he prescribed these controlled substances in this manner in order to preserve his patient's privacy

Indeed, nearly the entirety of the administrative record consists of items from Larson's criminal trial, including hearing transcripts and a copy of the complaint, and newspaper reports regarding the trial.

We are troubled by the fact that the Deputy Administrator went outside the papers submitted by Humphreys for evidence supporting his decision, such as Humphreys' pre-trial testimony - evidence that actually indicated that Humphreys acted out of concern for Larson's privacy - yet failed to obtain the public trial transcripts of Dr. Sandson and others from the very same trial, which were cited by Humphreys in his support, or to otherwise consider Humphreys' privacy defense. Such failure is especially egregious where, as here, the record is devoid of any evidence, in the form of affidavits, medical treatises or anything else, that would support a conclusion that doctors do not prescribe drugs in the name of proxies for famous patients with mental disorders in the "usual course" of their medical practice. Nor have we been able to locate any previous published DEA or court decision in which such privacy concerns were raised and rejected. Indeed, at oral argument the DEA representative acknowledged that she was unaware of any other proceeding in which such a privacy defense had been raised.

An agency's action is arbitrary and capricious if the agency "entirely failed to consider an important aspect of the problem, offered an explanation for its decision that runs counter to the evidence before the agency, or is so implausible that it could not be ascribed to a difference in view or the product of agency expertise." Natural Resources Defense Council, Inc. v. United States Env'tl. Protection Agency, 790 F.2d 289, 297-98 (3rd Cir. 1986) (quoting Motor Vehicle Mfrs. Ass'n. v. State Farm Mutual, 463 U.S. 29, 43 (1983)) (emphasis added), cert. denied sub nom. Chicago Ass'n. of Commerce & Indus. v. National Resources Defense Council, Inc., 479 U.S. 1084 (1987); see also Shane Meat Co. v. United States Dep't of Defense, 800 F.2d 334, 336 (3d Cir. 1986) ("Failure of the agency to address an important aspect of the issue under consideration may be fatal to its conclusion."). Here, the decision of the Deputy Administrator, lacking any analysis of Humphreys' privacy defense, is arbitrary and capricious.

In short, the Deputy Administrator both failed to evaluate and address Humphreys' defense and to resolve

the conflict created by the arguments and evidence before him. See *Kent v. Schweiker*, 710 F.2d 110, 114 (3d Cir. 1983) (stating, in reference to the substantial evidence test, that "[a] single piece of evidence will not satisfy the substantiality test if the Secretary ignores, or fails to resolve, a conflict created by countervailing evidence."). Humphreys and other trial witnesses asserted that such prescribing occurred in the "usual course," and there is no contrary evidence in the record. Thus, there is a conflict between the record evidence and the Deputy Administrator's tacit assumption about the "usual course" of medical practice. The Deputy Administrator nevertheless failed to resolve or even acknowledge this conflict. He neither gave any reasons for rejecting Humphreys' assertions about the "usual course," nor cited any evidence supporting the conclusion that Humphreys did not act in the "usual course." That he avoided this conflict is all the worse given his failure to review the public testimony that Humphreys and his attorney specifically cited, summarized and asserted would corroborate Humphreys' position.

It may well be that the testimony referred to by Humphreys and his attorney does not, in fact, establish that Humphreys was merely engaging in the "usual course" of practice. Here, however, the Deputy Administrator improperly failed to consider Humphreys' privacy concerns and failed to determine whether Humphreys' privacy concerns brought his otherwise allegedly improper prescribing conduct within the "usual course." Failing to analyze the privacy defense was an abuse of discretion. Absent such analysis, it was arbitrary and capricious to revoke Humphreys' registration in reliance on the second and fourth factors of 21 U.S.C. § 823(f).

We neither disregard nor minimize the substantial deference to which such agency decisions are always entitled. See *Pennsylvania Funeral Directors Ass'n. v. Federal Trade Comm'n.*, 41 F.3d 81, 85 (3d Cir. 1994) ("The arbitrary and capricious standard is very deferential."). We also recognize that we must not simply substitute our judgment for that of the agency. *Shane Meat Co.*, 800 F.2d at 336. However, this is not simply a case where we disagree with the Deputy Administrator's application of relevant mitigating aspects of the statutory factors to settled facts. See *Id.* (reversing district court decision finding an administrative decision arbitrary and capricious where the agency decision gave consideration to the relevant mitigating factors). Rather, here the agency improperly failed even to consider the defense put forth by Humphreys. The case must be remanded for proper consideration of that defense.

Proceedings on Remand

In addition to the Deputy Administrator's improper reliance on factors two and four in the absence of a

consideration of Humphreys' privacy defense, the Deputy Administrator's remaining discussion of the 21 U.S.C. § 823(f) factors contains several additional inconsistencies and problems which should be addressed and corrected on remand.

First, as to factor one, the "recommendation" of the appropriate state licensing board or professional disciplinary authority, section 823(f)(1), the Deputy Administrator noted that the Pennsylvania Bureau of Professional and Occupational Affairs had issued a Show Cause order alleging that Humphreys had engaged in a 12-year pattern of issuing prescriptions to individuals who were not his patients that, if proven, would violate state law and might justify revoking his medical license. At the time of DEA's decision, however, the only evidence in the record pertaining to the state investigation indicated merely that the Show Cause order had issued and that Pennsylvania bore the burden of proving the charges by a preponderance of the evidence. We have no indication whether Humphreys advanced the same defense there as here or what ruling, if any, Pennsylvania made on any such defense. On remand, the DEA should determine whether Pennsylvania, in fact, met its burden and what actions, if any, have actually been taken against Humphreys. If none, then the Deputy Administrator should consider whether, by merely issuing the Order to Show Cause, Pennsylvania authorities have made any "recommendation" within the meaning of section 823(f)(1). Only if the Deputy Administrator properly concludes Pennsylvania has made a "recommendation" of revocation or other punitive action may any weight adverse to Humphreys be given under factor one. Although in this decision the Deputy Administrator only gave limited weight to factor one, it is not clear any weight at all is appropriate.

Second, we note that, as applied by the Deputy Administrator, any weight under factor two, which concerns "experience with dispensing . . . controlled substances," is entirely dependent on the violation of a federal regulation found by the Deputy Administrator under factor four. That is, if Humphreys violated the federal regulation, that he did so for over 12 years is an aggravating factor. However, if his conduct was indeed in the "usual course," its duration is irrelevant.

Third, the DEA found that Humphreys' "prescribing of controlled substances to Justice Larson merely upon his request, without seeing him, examining him, or otherwise making a medical evaluation prior to issuing the prescription, demonstrated behavior such that the patient's demands seemed to replace the physician's judgment. . . . Such uncontroverted actions on the part of the Respondent are preponderating evidence that he has dispensed controlled substances in violation of federal law." We have reviewed the administrative record and

see nothing in the current record that would support this particular finding. While there is some evidence indicating Larson would call Humphreys and request prescriptions for certain drugs or request a change in his prescription, there is absolutely no testimony indicating Humphreys failed to exercise his own medical judgment when prescribing medication for Larson. We do not mean to say that the DEA might not be able to prove this fact at a later date upon an expanded record - only that it has not done so on this record. Indeed, if anything, the current record indicates Humphreys, in fact, was exercising independent medical judgment. Specifically, Humphreys stated that he would have adjusted the drugs accordingly had he become aware that other drugs were being prescribed to Larson by other doctors. Humphreys also testified that it was his belief that every medication he prescribed for Larson was medically appropriate. In addition, the testimony of Larson himself indicates Humphreys exercised his own judgment. Specifically, Larson testified Humphreys performed a full physical evaluation before prescribing drugs for the first time, that the drugs were later changed due to side effects, and that Humphreys was the "ultimate decider" of what particular drugs to prescribe. Thus, it remains unclear how factor four can weigh against Humphreys in this regard.

Fourth, the Deputy Administrator found, under factor five, that the public was at risk from the potential diversion of controlled substances by both Larson, who could have received duplicative prescriptions for controlled substances, and the employees named on the prescriptions, who were prescribed medication they did not intend to ingest and for which they themselves lacked a medical need. The Deputy Administrator's inferences of a threat of public harm are overly broad and only weakly, if at all, supported by the present record. Indeed, the Deputy Administrator admitted that no such diversion in fact occurred. The conclusion that substantial risk for diversion existed because Larson or the secretaries and the law clerk might resell the drugs, under these circumstances, is so unlikely as to be unsustainable. The secretaries and law clerk in whose names the prescriptions were written were, after all, trusted employees and responsible adults. They obtained the drugs at Larson's specific requests and under his instruction. Moreover, Larson was aware of what drugs he should receive from each of these individuals and when he should receive them, having contacted Humphreys each time to tell Humphreys which name to use for a particular prescription. Any deviation would have been quickly noticed and, presumably, dealt with appropriately. That such trusted employees were at risk because they might take the drugs themselves or endangered others because they might attempt to resell them, rather than turn them

over to Larson, is "implausible". See Natural Resources Defense Council, 790 F.2d at 297-98.

It is true, as the Deputy Administrator noted, that the pharmacist filling a prescription could not have checked any available computer data bank for conflicting prescriptions for Larson, since the prescriptions for Larson were not in his name. However, the DEA did not establish that the pharmacy or pharmacies patronized by Larson had such a system in place during the relevant time period. Moreover, if Larson frequented more than one pharmacy, the DEA has not shown that problems would have been detected even if all of Larson's prescriptions had been written in his own name.

Our discussion of the need on remand to correct the deficiencies in the decision under review should not be construed in any way as suggesting that Humphreys either is or is not entitled to retain his DEA registration. We intimate no view on that issue. Rather, we hold only that the Deputy Administrator failed to properly analyze the evidence and decide the issues and must do so on remand.

Conclusion

Because the DEA utterly failed to consider Humphreys' defense and improperly analyzed some of the evidence, its analysis was so inadequate and prejudicial to Humphreys as to constitute an abuse of discretion and render the revocation order an arbitrary and capricious agency action. Therefore, we vacate and remand.