United States Court of Appeals
FOR THE EIGHTH CIRCUIT

No. 03-1673

United States of America,	*	
	*	
Plaintiff - Appellant,	*	
	*	Appeal from the United States
v.	*	District Court for the
	*	Western District of Missouri.
Jackie Rae Springer; Gregory M. Chollet,	*	
	*	
	*	
Defendants - Appellees.	*	

Submitted: September 9, 2003

Filed: January 9, 2004

Before LOKEN, Chief Judge, McMILLIAN and HANSEN, Circuit Judges.

LOKEN, Chief Judge.

In 1997, the Food and Drug Administration (FDA) issued a public health advisory, warning that the diet drug fenfluramine may expose users to significantly increased risks of heart valve abnormalities. The drug's domestic manufacturer withdrew it from the U.S. market, and in March 1999 fenfluramine was formally listed as a "drug withdrawn or removed from the market for reasons of safety and effectiveness." 21 C.F.R. § 216.24. In September 2001, a Western District of Missouri grand jury issued a three-count indictment accusing Jackie Rae Springer and Gregory M. Chollet of purchasing fenfluramine in bulk quantities from a supplier in

the United Kingdom and concealing its importation with a false Customs declaration, all for the purpose of compounding the illegal drug into individual doses and distributing it in Kansas City. Springer and Chollet were charged with conspiring to import a controlled substance in violation of 18 U.S.C. § 371 and 21 U.S.C. §§ 952(b), 960(a)(1), and 960(b)(4); importation by false statement or declaration in violation of 18 U.S.C. § 542; and distribution of misbranded drugs in violation of 21 U.S.C. §§ 331(a) and 333(a)(2).

Defendants moved to dismiss Count One, the conspiracy count, on the ground that fenfluramine "was not a controlled substance at any time at issue in this case." The district court granted the motion. While acknowledging that fenfluramine continues to be listed as a controlled substance, the court noted that in 1996, before the FDA's public health advisory, the Secretary of Health and Human Services (the Secretary) recommended that fenfluramine be removed from the operative list, which is known as Schedule IV. The court concluded that fenfluramine "cannot be treated as a controlled substance" because the statute provides that "an HHS recommendation to 'decontrol' a drug is binding on the DEA and the Attorney General." The government appeals the dismissal of Count One. See 18 U.S.C. § 3731. Reviewing the district court's interpretation of the relevant statutes de novo, we reverse. See Ark. Blue Cross & Blue Shield v. St. Mary's Hosp., Inc., 947 F.2d 1341, 1344 (8th Cir. 1991), cert denied, 504 U.S. 957 (1992) (standard of review).

The federal food and drug laws prohibit knowingly or intentionally importing a controlled substance in a manner that violates 21 U.S.C. § 952. See 21 U.S.C. § 960(a)(1). Section 952(b) provides that it is unlawful "to import into the United States from any place outside thereof, any nonnarcotic controlled substance in schedule III, IV, or V" of subchapter I of Chapter 13 of Title 21. Congress codified the initial schedules in 21 U.S.C. § 812 and authorized the Attorney General to add or remove controlled substances from the schedules "by rule." 21 U.S.C. § 811(a).

In a 1973 rulemaking proceeding, the Attorney General added fenfluramine to the list of nonnarcotic controlled substances in Schedule IV. See Schedules of Controlled Substances, 38 Fed. Reg. 15719, 15721 (June 15, 1973). Springer and Chollet do not challenge that initial listing. In May 1997, in response to the Secretary's 1996 recommendation, the Attorney General (acting through the Drug Enforcement Administration) issued a proposed rule removing fenfluramine from Schedule IV. See Schedules of Controlled Substances, 62 Fed. Reg. 24620 (May 6, 1997). Two months later, the FDA issued its public health advisory. Presumably as a result of that regulatory action, the DEA rulemaking proceeding was suspended, and the proposed rule removing fenfluramine from Schedule IV never became final. Thus, fenfluramine was still listed in Schedule IV at the time of the events charged in the indictment. See 21 C.F.R. § 1308.14(d)(1).[1]

The issue in this case arises because of the role Congress gave the Secretary in the process of adding and removing drugs from the controlled substances schedules. The statute provides that the Attorney General may initiate a rulemaking proceeding to remove a controlled substance "if he finds that the drug or other substance does not meet the requirements for inclusion in any schedule." 21 U.S.C. § 811(a)(2). Before initiating a proceeding to add or remove a drug or substance:

> The Attorney General shall . . . request from the Secretary a scientific and medical evaluation, and his recommendations, as to whether such drug or other substance should be so controlled or removed as a controlled substance. . . . The recommendations of the Secretary to the Attorney General shall be binding on the Attorney General as to such scientific and medical matters, and *if the Secretary recommends that a drug or other substance not be controlled, the Attorney General shall not control the drug or other substance*. If the Attorney General determines that these facts and all other relevant data constitute

[1]The DEA has now withdrawn the proposed rule. See Schedules of Controlled Substances, 68 Fed. Reg. 26247 (May 15, 2003).

> substantial evidence . . . that the drug or other substance should be removed entirely from the schedules, he shall initiate proceedings for . . . removal . . . .

21 U.S.C. § 811(b) (emphasis added).

Springer and Chollet argue that the Secretary's 1996 recommendation was binding on the Attorney General under § 811(b), and therefore the Attorney General was *required* to remove fenfluramine from Schedule IV. The district court agreed with this contention, which the government strongly challenges on appeal. But to prevail on their motion to dismiss Count One, it is not enough for Springer and Chollet to establish that the Attorney General had a statutory duty to remove fenfluramine from Schedule IV "by rule." Such a removal proceeding was in process, but fenfluramine was still listed in Schedule IV when the defendants are alleged to have knowingly imported it. Therefore, Springer and Chollet also argue, as they must, that fenfluramine was no longer a "controlled substance" within the meaning of § 952(b), notwithstanding the fact that the DEA failed to complete the rulemaking process needed to remove it from Schedule IV. They cite no authority supporting this additional step in their statutory analysis. For purposes of § 952(b), "controlled substance" is defined to include any drug or other substance listed in Schedule IV. See 21 U.S.C. § 802(6), incorporated by reference in § 951(b).

Count One accuses Springer and Chollet of violating criminal statutes that punish the knowing importation of "any nonnarcotic controlled substance in schedule . . . IV." 21 U.S.C. § 952(b). These statutes create an offense *malum prohibitum*, that is, "[a]n act which is wrong only because made so by statute." Riss & Co. v. United States, 262 F.2d 245, 248 n.3 (8th Cir. 1958) (quotation omitted). Federal law has long prohibited the distribution of drugs enumerated in a statute. An indictment charging the violation of such a statute will be upheld if "the offense be described with sufficient clearness to show a violation of law, and to enable the accused to

know the nature and cause of the accusation." United States v. Behrman, 258 U.S. 280, 288 (1922); see generally Morissette v. United States, 342 U.S. 246, 250-63 (1952). Thus, if fenfluramine had been included in the initial statutory list of Schedule IV drugs, see 21 U.S.C. § 812(c), Count One would state a violation of § 952(b) *even if*, at the time of the events charged in the indictment, a bill had been pending in Congress to remove that drug from the statutory schedule.

The issue in this case is more complex because being listed in Schedule IV is an element of the § 952(b) offense *and* Congress delegated to the Secretary and the Attorney General the authority to add and remove drugs from Schedule IV. The Supreme Court has stated the general rule: "[W]here a determination made in an administrative proceeding is to play a critical role in the subsequent imposition of a criminal sanction, there must be *some* meaningful review of the administrative proceeding." United States v. Mendoza-Lopez, 481 U.S. 828, 837-38 (1987). The Controlled Substances Act provides for judicial review of the Attorney General's final decision to add or remove a drug from the schedules. See 21 U.S.C. § 877. Though this is "meaningful" pre-enforcement review, many circuits have reviewed the validity of a scheduling order when the issue was first raised as a defense to a criminal prosecution for unlawful distribution of the controlled substance, without considering whether a scheduling order that has become a final rule, without prior judicial review, should be treated the same as a *malum prohibitum* statutory violation. See United States v. Sullivan, 967 F.2d 370, 372-73 (10th Cir.), cert. denied, 506 U.S. 900 (1992); United States v. Roark, 924 F.2d 1426, 1428-29 (8th Cir. 1991); United States v. Kendall, 887 F.2d 240, 241 (9th Cir. 1989); United States v. Lueck, 678 F.2d 895, 904 (11th Cir. 1982); United States v. Roya, 574 F.2d 386, 392-93 (7th Cir.), cert. denied, 439 U.S. 857 (1978). By contrast, in Touby v. United States, 500 U.S. 160, 168-69 (1991), the Supreme Court adopted a narrower view, agreeing with the government that the validity of a *temporary* scheduling order may be challenged as a defense to a criminal prosecution only because the Controlled Substances Act

expressly precludes pre-enforcement judicial review of temporary orders. See 21 U.S.C. § 811(h)(6).

We assume without deciding that the Attorney General's final decision to add fenfluramine to Schedule IV by rule may be challenged by the defendant in a § 952(b) prosecution, as prior circuit court decisions have permitted. Presumably, the Attorney General's final decision not to remove fenfluramine from Schedule IV would be subject to the same judicial review. But Springer and Chollet do not challenge a final agency decision to continue controlling fenfluramine. Rather, they argue that the § 952(b) indictment in this case is invalid because a validly scheduled drug *should be deemed to have been removed* from Schedule IV, despite the *lack of* final agency action. The district court agreed, concluding that the proposed rule removing fenfluramine from Schedule IV must be treated as a final rule because the Attorney General was bound by the provision in § 811(b) that he "shall not control" a drug if the Secretary has recommended that it not be controlled.

In our view, the district court erred in treating the Secretary's recommendation as final. Upon receiving that recommendation, the Attorney General proposed a rule removing fenfluramine from Schedule IV. A major purpose of formal rulemaking is to ensure that agencies gather as much relevant information as possible before promulgating final rules that will have the force and effect of law. For this reason, an agency that exercises its discretion to propose a rule has no duty to promulgate its proposal as a final rule. Thus, it is well-settled "that proposed regulations . . . have no legal effect." Sweet v. Sheahan, 235 F.3d 80, 87 (2d Cir. 2000); see Commodity Futures Trading Comm'n v. Schor, 478 U.S. 833, 845 (1986).

This principle does not change when Congress mandates that two agencies participate in the rulemaking process and assigns one agency the dominant role as to one or more issues. Whichever agency has the discretion to propose or recommend an action likewise has the discretion to change its mind before the final rule is

promulgated. Here, at the time of the events charged in Count One, the rulemaking was in progress, not completed. The Secretary was an interested party to that proceeding, and nothing in the statute prevented the Secretary from modifying his initial recommendation before a final rule was promulgated or the proceeding was otherwise terminated. Thus, the incomplete rulemaking lacked a final agency action by the Secretary recommending that fenfluramine be removed from Schedule IV. In these circumstances, the district court erred in concluding that the Attorney General's proposed rule must be given the force and effect of law based upon the Secretary's initial recommendation.

For these reasons, fenfluramine was a Schedule IV controlled substance for purposes of 21 U.S.C. § 952(b) at the time in question. Count One must therefore be upheld. The district court's dismissal order is reversed.
