

**AMENDMENT TO RULES COMMITTEE PRINT 119-3**  
**OFFERED BY MS. DEAN OF PENNSYLVANIA**

At the end of subtitle B of title XVII, insert the following new section:

1 **SEC. 17\_\_\_ . SPECIAL REGISTRATION REQUIREMENTS RE-**  
2 **LATED TO RIGHT TO TRY.**

3 Section 303 of the Controlled Substances Act (21  
4 U.S.C. 823) is amended by adding at the end the following:  
5

6 “(p) SPECIAL REGISTRATION FOR SCHEDULE I ELI-  
7 GIBLE INVESTIGATIONAL DRUGS UNDER RIGHT TO  
8 TRY.—

9 “(1) DEFINITIONS.—In this subsection, the  
10 terms ‘eligible investigational drug’ and ‘eligible pa-  
11 tient’ have the meanings given those terms in section  
12 561B of the Federal Food, Drug, and Cosmetic Act  
13 (21 U.S.C. 360bbb–0a).

14 “(2) SPECIAL REGISTRATION PROCESS.—The  
15 Attorney General shall register physicians to directly  
16 administer eligible investigational drugs in schedule  
17 I to eligible patients under section 561B of the Fed-  
18 eral Food, Drug, and Cosmetic Act (21 U.S.C.

1 360bbb-0a) in accordance with paragraphs (3)  
2 through (8) of this subsection.

3 “(3) REQUIREMENTS.—

4 “(A) APPLICATION.—A physician desiring  
5 a registration to directly administer an eligible  
6 investigational drug as described in paragraph  
7 (2) shall submit to the Attorney General an ap-  
8 plication containing—

9 “(i) evidence of a valid registration to  
10 dispense or administer controlled sub-  
11 stances in schedules II through V;

12 “(ii) evidence of compliance with sec-  
13 tion 561B of the Federal Food, Drug, and  
14 Cosmetic Act (21 U.S.C. 360bbb-0a), in-  
15 cluding—

16 “(I) documentation from the  
17 manufacturer or sponsor verifying the  
18 investigational drug in schedule I is  
19 an eligible investigational drug;

20 “(II) an agreement from the  
21 manufacturer or sponsor to supply the  
22 eligible investigational drug, along  
23 with guidance on its administration,  
24 to the requesting physician for the  
25 treatment of eligible patients; and

1                   “(III) an affirmation that the  
2                   physician will only directly administer  
3                   the eligible investigational drug to  
4                   treat eligible patients in a manner  
5                   consistent with the guidance provided  
6                   by the manufacturer or sponsor;

7                   “(iii) the quantity of the eligible inves-  
8                   tigational drug to be supplied by the man-  
9                   ufacturer or sponsor to the physician to  
10                  treat eligible patients;

11                  “(iv) evidence that the physician may  
12                  treat eligible patients with eligible inves-  
13                  tigational drugs under the laws of the  
14                  State in which the treatment will take  
15                  place;

16                  “(v) evidence of training, credentials,  
17                  or experience relevant to treating patients  
18                  with the eligible investigational drug;

19                  “(vi) a description of the site at which  
20                  the physician intends to store and admin-  
21                  ister the eligible investigational drug; and

22                  “(vii) any additional information the  
23                  Attorney General determines necessary to  
24                  prevent diversion.

1           “(B) APPROVAL.—Not later than 45 days  
2           after receiving an application containing the in-  
3           formation required under subparagraph (A), the  
4           Attorney General shall—

5                   “(i) register the applicant; or

6                   “(ii) serve an order to show cause  
7           upon the applicant in accordance with sec-  
8           tion 304(c).

9           “(4) ELECTRONIC SUBMISSIONS.—The Attorney  
10          General shall provide a means for a physician to  
11          submit an application under paragraph (3)(A) elec-  
12          tronically.

13          “(5) LIMITATION ON AMOUNTS.—A physician  
14          treating eligible patients with an eligible investiga-  
15          tional drug in schedule I under this subsection may  
16          only possess the amounts of the eligible investiga-  
17          tional drug identified in—

18                   “(A) the application submitted to the At-  
19                  torney General under paragraph (3)(A); or

20                   “(B) a supplemental notification that the  
21                  physician may submit to the Attorney General  
22                  if the physician needs additional amounts of the  
23                  eligible investigational drug for the treatment of  
24                  eligible patients, which supplemental notifica-  
25                  tion—

1 “(i) shall include—

2 “(I) the name of the physician;

3 “(II) the additional quantity of  
4 the eligible investigational drug need-  
5 ed; and

6 “(III) an attestation that the  
7 treatment with the eligible investiga-  
8 tional drug is consistent with the  
9 scope of treatment that was the sub-  
10 ject of the application under para-  
11 graph (3)(A); and

12 “(ii) shall be deemed approved on the  
13 date that is 30 days after the date on  
14 which the physician submits the supple-  
15 mental notification to the Attorney Gen-  
16 eral, unless the Attorney General serves an  
17 order to show cause upon the applicant in  
18 accordance with section 304(c).

19 “(6) SINGLE REGISTRATION FOR RELATED  
20 TREATMENT SITES.—A physician may treat eligible  
21 patients with an eligible investigational drug in  
22 schedule I under a single registration under this  
23 subsection if—

24 “(A) the treatment occurs exclusively on  
25 sites all of which are—

1 “(i) within the same city or county;

2 and

3 “(ii) under the control of the same in-  
4 stitution, organization, or agency; and

5 “(B) before commencing the treatment, the  
6 physician notifies the Attorney General of each  
7 site where the eligible investigational drug will  
8 be stored or administered in accordance with  
9 paragraph (3)(A)(vi).

10 “(7) RULEMAKING.—Notwithstanding the re-  
11 quirements of section 553 of title 5, United States  
12 Code, not later than 240 days after the date of en-  
13 actment of this subsection, the Attorney General  
14 shall issue an interim final rule to implement this  
15 subsection, including with respect to—

16 “(A) the manner in which an eligible inves-  
17 tigational drug may be delivered to an approved  
18 registrant;

19 “(B) the storage and security of an eligible  
20 investigational drug;

21 “(C) the maintenance of records for an ap-  
22 proved registrant;

23 “(D) the process for renewal, suspension,  
24 or revocation of a registration; and

1                   “(E) any other matters necessary to en-  
2                   sure effective controls against diversion.

3                   “(8) FINAL RULE.—Not later than 2 years  
4                   after issuing an interim final rule under paragraph  
5                   (7), the Attorney General shall issue a final rule to  
6                   implement this subsection in accordance with section  
7                   553 of title 5, United States Code.”.

