

119TH CONGRESS  
2D SESSION

# H. R. 10088

To direct the Secretary of Health and Human Services, acting through the Commissioner of Food and Drugs, to conduct a study to assess the potential for expanding the safe and effective use of reprocessed single-use devices, and for other purposes.

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## IN THE HOUSE OF REPRESENTATIVES

AUGUST 13, 2026

Mrs. FOUSHEE introduced the following bill; which was referred to the  
Committee on Energy and Commerce

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## A BILL

To direct the Secretary of Health and Human Services, acting through the Commissioner of Food and Drugs, to conduct a study to assess the potential for expanding the safe and effective use of reprocessed single-use devices, and for other purposes.

1       *Be it enacted by the Senate and House of Representa-*  
2       *tives of the United States of America in Congress assembled,*

3       **SECTION 1. REPROCESSING OF SINGLE-USE DEVICES.**

4       (a) STUDY.—The Secretary of Health and Human  
5       Services, acting through the Commissioner of Food and  
6       Drugs (in this section referred to as the “Secretary”),

1 shall conduct a study to assess the potential for expanding  
2 the safe and effective use of reprocessed single-use devices.

3 (b) PRIMARY CRITERIA.—In conducting the study  
4 under subsection (a), the Secretary shall ensure that pa-  
5 tient safety and infection prevention are the primary cri-  
6 teria used in examining the potential for reprocessing sin-  
7 gle-use devices, with stratification by risk category and  
8 clinical use.

9 (c) FOCUS ON THIRD-PARTY REPROCESSORS.—In  
10 conducting the study under subsection (a), the Secretary  
11 shall evaluate opportunities for, and barriers to, the ex-  
12 panded use of qualified third-party reprocessors.

13 (d) CONTENTS.—In conducting the study under sub-  
14 section (a), the Secretary shall examine, at a minimum—

15 (1) existing pathways of the Food and Drug  
16 Administration for the reprocessing of single-use de-  
17 vices, including instances in which current rules are  
18 sufficient and instances in which barriers exist;

19 (2) the role of third-party reprocessors of sin-  
20 gle-use devices versus in-house hospital reprocessing;

21 (3) the operational feasibility of reprocessing  
22 single-use devices, including sterile processing capac-  
23 ity, staffing, equipment, chain of custody, tracking,  
24 and quality assurance;

1           (4) the financial and environmental return of  
2       reprocessing single-use devices, taking into consider-  
3       ation waste reduction, cost savings, and any added  
4       labor, capital, or compliance burden; and

5           (5) issues related to liability and accountability  
6       if a reprocessed single-use device fails or contributes  
7       to patient harm.

8       (e) CONSIDERATIONS.—In conducting the study  
9       under subsection (a), the Secretary shall consider, with re-  
10      spect to the reprocessing of single-use devices—

11           (1) clinical outcomes and device performance;

12           (2) validated reprocessing-cycle limits;

13           (3) collection and transportation logistics;

14           (4) the percentage of collected devices that can  
15      be reprocessed;

16           (5) contractual or technical barriers; and

17           (6) full lifecycle financial and environmental im-  
18      pact.

19       (f) CONSULTATION.—In conducting the study under  
20      subsection (a), the Secretary shall seek input from—

21           (1) non-Federal entities, including hospitals,  
22      supply chain leaders, infection prevention organiza-  
23      tions, sterile processing organizations, clinicians, and  
24      appropriate industry representatives; and

1           (2) Federal entities, including the Food and  
2       Drug Administration, the Centers for Disease Con-  
3       trol and Prevention, and the Centers for Medicare &  
4       Medicaid Services.

5       (g) DEFINITIONS.—In this section, the terms “de-  
6       vice”, “reprocessed”, and “single-use device” have the  
7       meanings given such terms in section 201 of the Federal  
8       Food, Drug, and Cosmetic Act (21 U.S.C. 321).

9       (h) REPORT TO CONGRESS.—Not later than 1 year  
10      after the date of enactment of this Act, the Secretary shall  
11      transmit to Congress a report on the results of the study,  
12      including—

13           (1) a listing of single-use devices that the Sec-  
14      retary determines have the potential for reprocess-  
15      ing, including an identification of—

16                   (A) devices currently legally marketed for  
17                   reprocessing;

18                   (B) devices for which reprocessing is sup-  
19                   ported by sufficient evidence; and

20                   (C) devices for which reprocessing requires  
21                   further research; and

22           (2) recommendations for programs and activi-  
23      ties to provide for such reprocessing, including the  
24      use of—

25                   (A) qualified third-party reprocessors;

- 1                   (B) appropriate cleaning and sterilization
- 2                   technology;
- 3                   (C) quality assurance and tracking sys-
- 4                   tems; and
- 5                   (D) infection prevention controls.

