

AMENDMENT TO RULES COMMITTEE PRINT 119-

16

OFFERED BY MR. FINE OF FLORIDA

At the end of title XVII, add the following new section:

1 SEC. 17____. STOCKPILING OF LYMPHOCYTE-STIMULATING
2 AGENTS FOR NATIONAL DEFENSE AND PUB-
3 LIC HEALTH PREPAREDNESS.

4 (a) FINDINGS.—Congress finds the following:

5 (1) Lymphopenia, defined by an absolute lymphocyte count below $1.0 \times 10^3/\mu\text{L}$, is a major predictor of mortality in radiation injury, chemical exposure, infectious disease outbreaks, and critical illness, including sepsis and acute respiratory distress.

10 (2) Rapid restoration of lymphocyte populations, including natural killer (NK) and CD8+ T cells, is essential for survival following high-risk exposures relevant to national defense, including radiological events, biological threats, and emerging infectious pathogens.

16 (3) Lymphocyte-Stimulating Agents (LSAs), including interleukin-15 receptor agonists capable of expanding NK and CD8+ T cells, have dem-

1 onstrated the ability to reverse lymphopenia and re-
2 store cytotoxic lymphocyte populations necessary for
3 pathogen and tumor clearance.

4 (4) The Department of Defense, in coordination
5 with the Department of Health and Human Serv-
6 ices, requires sustained access to LSAs as a core
7 component of national biodefense and force protec-
8 tion.

9 (b) DEFINITION.—For the purposes of this section,
10 the term “Lymphocyte-Stimulating Agent” (LSA) means
11 a biologic product that—

12 (1) is an interleukin-15 (IL-15) and IL-15 re-
13 ceptor alpha (IL-15R α) superagonist fusion protein
14 or functionally equivalent biologic;

15 (2) demonstrates expansion of NK cells and T
16 cells in humans; and

17 (3) is authorized for commercial distribution by
18 the Food and Drug Administration or made avail-
19 able under section 564 of the Federal Food, Drug,
20 and Cosmetic Act or any successor authority.

21 (c) MEDICAL COUNTERMEASURE REQUIREMENT.—
22 The Secretary of Defense, acting through the Assistant
23 Secretary of Defense for Health Affairs and in coordina-
24 tion with the Assistant Secretary for Preparedness and

1 Response of the Department of Health and Human Serv-
2 ices, shall—

3 (1) establish and maintain a strategic reserve of
4 Lymphocyte-Stimulating Agents sufficient to sup-
5 port deployment, force protection, and civilian emer-
6 gency response;

7 (2) ensure that LSAs are integrated into Chem-
8 ical, Biological, Radiological, and Nuclear (CBRN)
9 response protocols, including radiological exposure
10 and emerging biological threats;

11 (3) support procurement, storage, and lifecycle
12 management of LSAs under the authorities of the
13 Public Health Emergency Medical Countermeasures
14 Enterprise (PHEMCE) and the Biomedical Ad-
15 vanced Research and Development Authority
16 (BARDA); and

17 (4) conduct periodic readiness assessments to
18 ensure the strategic reserve is adequate to meet mo-
19 bilization requirements for military personnel and ci-
20 vilian support.

21 (d) RESEARCH, DEVELOPMENT, AND FIELD EVAL-
22 UATION.—

23 (1) CONTRACTS AND OTHER AGREEMENTS.—

24 The Secretary of Defense may enter into contracts,
25 cooperative agreements, or other transactions with

1 public or private entities to evaluate LSAs for pre-
2 vention or mitigation of lymphopenia associated with
3 radiation exposure, biological threat agents, or oper-
4 ational stress.

5 (2) COORDINATION.—The Secretary of Defense
6 shall coordinate with the Director of the National
7 Institutes of Health and the Commissioner of Food
8 and Drugs to support clinical studies validating lym-
9 phocyte restoration as a biomarker of survival in de-
10 fense-relevant exposures.

11 (e) REPORT TO CONGRESS.—Not later than 180 days
12 after the date of the enactment of this Act, the Secretary
13 of Defense, in coordination with the Secretary of Health
14 and Human Services, shall submit a report to the Commit-
15 tees on Armed Services of the Senate and House of Rep-
16 resentatives describing—

17 (1) procurement plans and estimated quantities
18 of LSAs required for national defense stockpiling;

19 (2) integration of LSAs into CBRN medical
20 countermeasure frameworks; and

21 (3) projected cost savings and force-readiness
22 benefits from mortality reduction associated with
23 rapid reversal of lymphopenia.

1 (f) AUTHORIZATION OF APPROPRIATIONS.—There
2 are authorized to be appropriated such sums as may be
3 necessary to carry out this section.

