AMENDMENT TO
RULES COMMITTEE PRINT 118–10
OFFERED BY MS. DE LAURO OF CONNECTICUT

Add at the end of title XVIII the following:

SEC. ______. PROHIBITING ACQUISITION OF OR PAYMENT FOR PHARMACEUTICALS NOT MANUFACTURED IN FACILITIES IN COMPLIANCE WITH FEDERAL STANDARDS.

(a) Prohibition.—

(1) In general.—The Secretary of Defense may not purchase or otherwise obtain, and may not include on the uniform formulary of pharmaceutical agents under the pharmacy benefits program established under section 1074g of title 10, United States Code, any pharmaceutical agent which is manufactured, or for which any of its active pharmaceutical ingredients is manufactured, in a facility which is not a certified facility.

(2) Exceptions.—Paragraph (1) does not apply with respect to a pharmaceutical agent if—

(A) the Secretary, in consultation with the Director of the Food and Drug Administration, finds that the agent is not available from cer-
tified facilities in sufficient quantities to meet
the needs of the Secretary; or

(B) the agent, or any of its active pharma-
ceutical ingredients which is not manufactured
in a certified facility, has been tested and cer-
tified as safe by an accredited independent lab-
oratory which tests pharmaceutical agents and
their active pharmaceutical ingredients and cer-
tifies their safety, but only if the testing is
based on samples obtained by the laboratory
from a source other than the manufacturer of
the agent or its ingredient.

(b) INVESTIGATION AND REPORT ON SAFETY OF
CHINESE FACILITIES.—

(1) INVESTIGATION.—The Director of the Food
and Drug Administration shall conduct an investiga-
tion to determine whether facilities in the People’s
Republic of China which manufacture pharma-
ceutical agents and their active pharmaceutical in-
gredients, as regulated by the Food and Drug Ad-
ministration, meet the same health and safety stand-
ards required of facilities in the United States.

(2) REPORT TO CONGRESS.—Not later than 6
months after the date of the enactment of this Act,
the Director of the Food and Drug Administra-

(A) shall certify to Congress that, on the
basis of the investigation conducted under para-
graph (1), facilities in the People’s Republic of
China which manufacture pharmaceutical
agents and their active pharmaceutical ingredi-
ents meet health and safety standards which
are substantially the same as the standards met
by facilities in the United States; or

(B) submit a report to Congress on a plan
for protecting individuals who use pharma-
aceutical agents provided by or paid for by the
Secretary of Defense from unsafe or contami-
nated agents manufactured in the People’s Re-
public of China.

(c) DEFINITIONS.—In this section, the following defi-
nitions apply:

(1) ACCREDITED INDEPENDENT LABORA-
TORY.—The term “accredited independent labora-
tory” means a facility accredited to ISO 17025 or
equivalent standards and not accredited to cGMP to
ensure no conflicts of interest and whose accredita-
tion is current and in compliance with an appro-
priate accreditation body for the testing of pharma-
(2) **ACTIVE PHARMACEUTICAL INGREDIENT.**—The term “active pharmaceutical ingredient” has the meaning given such term in section 207.1 of title 21, Code of Federal Regulations, or any successor regulation promulgated by the Director of the Food and Drug Administration.

(3) **CERTIFIED FACILITY DEFINED.**—The term “certified facility” means a facility which the Director of the Food and Drug Administration certifies, on the basis of an on-site inspection conducted by the Food and Drug Administration, to be in compliance with all applicable health and safety standards of the Food and Drug Administration for facilities engaged in the manufacture of pharmaceutical agents and their active pharmaceutical ingredients, including standards requiring active and ongoing monitoring and testing of such agents and their active pharmaceutical ingredients.

(4) **PHARMACEUTICAL AGENT DEFINED.**—The term “pharmaceutical agent” means drugs, biological products, and medical devices under the regu-
latory authority of the Food and Drug Administra-
tion.