

AMENDMENT TO COMMITTEE PRINT
OFFERED BY MR. MATHESON OF UTAH
(REMS_001, June 11, 2007)

At the appropriate place in the bill, insert the following new sections (and make such technical and conforming changes as may be necessary):

1 **SEC. ____ . IDENTIFICATION OF CLINICALLY SUSCEPTIBLE**
2 **CONCENTRATIONS OF ANTIMICROBIALS.**

3 (a) DEFINITION.—In this section, the term “clinically
4 susceptible concentrations” means specific values which
5 characterize microbial organisms, including bacteria,
6 fungi, viruses, and parasites, as clinically susceptible, in-
7 termediate, or resistant to the drug (or drugs) tested.

8 (b) IDENTIFICATION.—The Secretary of Health and
9 Human Services (referred to in this section as the “Sec-
10 retary”), acting through the Commissioner of Food and
11 Drugs, shall identify and periodically update clinically sus-
12 ceptible concentrations of antimicrobial drugs.

13 (c) PUBLIC AVAILABILITY.—The Secretary, acting
14 through the Commissioner of Food and Drugs, shall make
15 such concentrations publicly available within 30 days of
16 the date of identification and any update under this sec-
17 tion.

1 (d) EFFECT.—Nothing in this section shall be con-
2 strued to restrict, in any manner, the prescribing of anti-
3 biotics by physicians, or to limit the practice of medicine,
4 including for diseases such as Lyme and tick-borne dis-
5 eases.

6 **SEC. ____ . ORPHAN ANTIBIOTIC DRUGS.**

7 (a) PUBLIC MEETING.—The Commissioner of Food
8 and Drugs shall convene a public meeting and, if appro-
9 priate, issue guidance, regarding which serious and life
10 threatening infectious diseases, such as diseases due to
11 gram-negative bacteria and other diseases due to anti-
12 biotic-resistant bacteria, potentially qualify for available
13 grants and contracts under section 5(a) of the Orphan
14 Drug Act (21 U.S.C. 360ee(a)) or other incentives for de-
15 velopment.

16 (b) GRANTS AND CONTRACTS FOR THE DEVELOP-
17 MENT OF ORPHAN DRUGS.—Section 5(c) of the Orphan
18 Drug Act (21 U.S.C. 360ee(c)) is amended to read as fol-
19 lows:

20 “(c) For grants and contracts under subsection (a),
21 there are authorized to be appropriated \$35,000,000 for
22 each of fiscal years 2008 through 2012.”.