

1 **SEC. 2102. FACILITATING RESPONSIBLE COMMUNICATION**
2 **OF SCIENTIFIC AND MEDICAL DEVELOP-**
3 **MENTS.**

4 (a) GUIDANCE.—Not later than 18 months after the
5 date of enactment of this Act, the Secretary of Health and
6 Human Services shall issue draft guidance on facilitating
7 the dissemination of responsible, truthful, and non-mis-
8 leading scientific and medical information not included on
9 the label of drugs.

10 (b) DEFINITION.—In this section, the term “drug”
11 has the meaning given to such term in section 201 of the
12 Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321).

13 **Subtitle G—Antibiotic Drug**
14 **Development**

15 **SEC. 2121. APPROVAL OF CERTAIN DRUGS FOR USE IN A**
16 **LIMITED POPULATION OF PATIENTS.**

17 (a) PURPOSE.—The purpose of this section is to help
18 expedite the development and availability of treatments for
19 serious or life-threatening bacterial or fungal infections in
20 patients with unmet needs, while maintaining safety and
21 effectiveness standards for such treatments, taking into
22 account the severity of the infection and the availability
23 or lack of alternative treatments.

24 (b) APPROVAL OF CERTAIN ANTIBACTERIAL AND
25 ANTIFUNGAL DRUGS.—Section 505 of the Federal Food,
26 Drug, and Cosmetic Act (21 U.S.C. 355), as amended by