

EXHIBIT S

**TO DECLARATION OF
JENNIFER A. SORENSON**

FDA Consumer Health Information (2010)

Combating Antibiotic Resistance

Antibiotics are drugs used for treating infections caused by bacteria. Also known as antimicrobial drugs, antibiotics have saved countless lives.

Misuse and overuse of these drugs, however, have contributed to a phenomenon known as antibiotic resistance. This resistance develops when potentially harmful bacteria change in a way that reduces or eliminates the effectiveness of antibiotics.

A Public Health Issue

Antibiotic resistance is a growing public health concern worldwide. When a person is infected with an antibiotic-resistant bacterium, not only is treatment of that patient more difficult, but the antibiotic-resistant bacterium may spread to other people.

When antibiotics don't work, the result can be

- longer illnesses
- more complicated illnesses
- more doctor visits
- the use of stronger and more expensive drugs
- more deaths caused by bacterial infections

Examples of the types of bacteria that have become resistant to antibiotics include the species that cause skin infections, meningitis, sexually transmitted diseases and respiratory tract infections such as pneumonia.

In cooperation with other government agencies, the Food and Drug Administration (FDA) has launched several initiatives to address antibiotic resistance.

The agency has issued drug labeling regulations, emphasizing the prudent use of antibiotics. The regulations encourage health care professionals to prescribe antibiotics only when clinically necessary, and to coun-



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Health care professionals should prescribe antibiotics only for infections they believe to be caused by bacteria. Patients should not demand antibiotics when a health care professional says the drugs are not needed.

sel patients about the proper use of such drugs and the importance of taking them as directed. FDA has also encouraged the development of new drugs, vaccines, and improved tests for infectious diseases.

Antibiotics Fight Bacteria, Not Viruses

Antibiotics are meant to be used against bacterial infections. For example, they are used to treat strep throat, which is caused by streptococcal bacteria, and skin infections caused by staphylococcal bacteria.

Although antibiotics kill bacteria, they are not effec-

Although antibiotics kill bacteria, they are not effective against viruses.

tive against viruses. Therefore, they will not be effective against viral infections such as colds, most coughs, many types of sore throat, and influenza (flu).

Using antibiotics against viral infections

- will not cure the infection
- will not keep other individuals from catching the virus
- will not help a person feel better
- may cause unnecessary, harmful side effects
- may contribute to the development of antibiotic-resistant bacteria

Patients and health care professionals alike can play an important role in combating antibiotic resistance. Patients should not demand antibiotics when a health care professional says the drugs are not needed. Health care professionals should prescribe antibiotics only for infections they believe to be caused by bacteria.

As a patient, your best approach is to ask your health care professional whether an antibiotic is likely to be effective for your condition. Also, ask what else you can do to relieve your symptoms.

Follow Directions for Proper Use

When you are prescribed an antibiotic to treat a bacterial infection, it's important to take the medication exactly as directed. Here are more tips to promote proper use of antibiotics.

- **Complete the full course of the drug.** It's important to take all of the medication, even if you are feeling better. If treatment stops too soon,

the drug may not kill all the bacteria. You may become sick again, and the remaining bacteria may become resistant to the antibiotic that you've taken.

- **Do not skip doses.** Antibiotics are most effective when they are taken regularly.
- **Do not save antibiotics.** You might think that you can save an antibiotic for the next time you get sick, but an antibiotic is meant for your particular infection at the time. Never take leftover medicine. Taking the wrong medicine can delay getting the appropriate treatment and may allow your condition to worsen.
- **Do not take antibiotics prescribed for someone else.** These may not be appropriate for your illness, may delay correct treatment, and may allow your condition to worsen.
- **Talk with your health care professional.** Ask questions, especially if you are uncertain about when an antibiotic is appropriate or how to take it.

It's important that you let your health care professional know of any troublesome side effects. Consumers and health care professionals can also report adverse events to FDA's MedWatch program at 800-FDA-1088 or online at www.fda.gov/medwatch/report.htm.

What FDA Is Doing

FDA combating antibiotic resistance through activities that include

- **Labeling regulations addressing proper use of antibiotics.** Antibiotic labeling contains required

statements in several places advising health care professionals that these drugs should be used only to treat infections that are believed to be caused by bacteria. Labeling also encourages health care professionals to counsel patients about proper use.

- **Partnering to promote public awareness.** FDA is partnering with the Centers for Disease Control and Prevention (CDC) on "Get Smart: Know When Antibiotics Work," a campaign that offers Web pages, brochures, fact sheets, and other information sources aimed at helping the public learn about preventing antibiotic-resistant infections.
- **Encouraging the development of new antibiotics.** FDA is actively engaged in developing guidance for industry on the types of clinical studies that could be performed to evaluate how an antibacterial drug works for the treatment of different types of infections. [FDA](#)

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