# EXHIBIT BB

#### TO DECLARATION OF JENNIFER A. SORENSON

WHO World Health Day 2011 FAQ

### World Health Day 2011



### **Frequently Asked Questions**

### 1. What is antimicrobial resistance, commonly known as drug resistance? What is the difference between antibiotic, antimicrobial and antiretroviral resistance or so called "superbugs"?

> Drug resistance (also known as antimicrobial resistance) is the natural process through which disease organisms – bacteria, viruses, parasites, fungi and other pathogens – develop resistance over time to the medicines used to treat them. As resistance develops, these medicines become progressively less effective – and eventually they lose their effectiveness. Drug resistance is a consequence of the use, and particularly the misuse, of antimicrobial medicines. "Superbugs" is the name often given to pathogens found in hospitals that acquire resistance to all standard antimicrobials. This is concerning and is the reason why rational use of antimicrobial drugs is so important.

#### 2. Why has WHO chosen drug resistance as the theme of this year's World Health Day?

> Drug resistance is becoming more dangerous, as more microorganisms develop or acquire resistance to the medicines used to treat them. Modern healthcare depends substantially on antibiotics and other antimicrobial medicines to treat conditions that would previously have proved fatal. Today, there is more resistance – and there are fewer new antimicrobial medicines in the pipeline – than ever before. That is why WHO is calling on governments to take urgent action to prevent and control drug resistance.

#### 3. Why is drug resistance a global concern?

> The development of resistance to drugs used to treat infections threatens our ability to treat disease and to protect the advances made in global health in recent decades. The invention of antibiotics and other antimicrobial drugs has changed the course of human history. People in every country today have benefitted from the development of antimicrobials. But their effectiveness is under threat. We must do everything in our power to preserve these drugs for future generations. Some of the greatest achievements of global health -- treating tuberculosis, malaria, HIV, pneumonia, diarrhoea and other killer infectious diseases -- are at risk as drug resistance rises. Without effective drugs, we cannot prevent death and disease; the world risks losing the progress that's been made on the Millennium Development Goals.

#### 4. What will WHO be doing on World Health Day 2011?

> On World Health Day, WHO will be calling for intensified global commitment to safeguard antimicrobial medicines for future generations. WHO will introduce a policy package setting out what governments and others can do to combat the spread of drug resistance. These are the key policy measures:

For more information, go to: http://www.who.int/world-health-day/2011

### **COMBAT DRUG RESISTANCE** No action today, no cure tomorrow

- Commit to a comprehensive, financed national plan with accountability and civil society engagement;
- Strengthen disease surveillance and laboratory capacity;
- Ensure uninterrupted access to essential medicines of assured quality;
- Regulate and promote rational use of medicines, including in animal husbandry, and ensure proper patient care;
- Enhance infection prevention and control;
- Foster innovations, and research and development of new tools.

#### 5. What can governments do?

> Governments can take the lead by introducing comprehensive policies to prevent the emergence of drug resistance and ensuring these policies are adequately resourced.

#### 6. What can consumers do?

> Antimicrobial drugs are a precious resource for everyone on the planet. Like any global good, we have a responsibility to protect this resource and to use it responsibly. Consumers can help by only using antibiotics and other antimicrobial drugs when they are prescribed for use, and always completing courses of medicine. When people only take part of a course of treatment, this contributes to the development of drug resistance.

#### 7. What can doctors do?

> Doctors can come under pressure from patients and inappropriate pharmaceutical marketing to prescribe medicines when it may not be necessary. It is important that all health professionals, including doctors, resist this pressure. Doctors can help by explaining to their patients when antibiotics and other antimicrobial drugs are appropriate, and when they are not. Also, doctors can inform their patients of the benefits of completing a course of medicine when it is prescribed, rather than stopping the treatment as soon as they start to feel better.

#### 8. What can pharmacists do?

> Pharmacists have an especially important role to play, because in most settings they are the ones distributing antimicrobial medicines to patients. Like other health professionals, pharmacists can ensure that patients understand the importance of taking only the medicines that are prescribed to them, and completing the full course of treatment.

#### 9. What can the pharmaceutical industry do?

> The research and development of new medicines is vital to help protect future generations. As drug resistance develops, new medicines are needed, as well as new ways of using existing medicines. Currently, there are very few new antimicrobial medicines, diagnostics or vaccines in the R&D pipeline. For example, fewer than five per cent of drugs currently in the pipeline are new antibiotics. The industry should engage with partners to overcome the barriers to R&D. Better incentives are also needed to encourage more R&D into this vital area.

## 10. What should governments and others do to provide incentives for research and development of new antimicrobial drugs?

> This is an important issue and in fact this week (April 5 - 7) WHO is hosting the first meeting of the Consultative Expert Working Group on Research and Development: Financing and Coordination. The work of this group, its findings and methods, will be available via the WHO Public Health, Innovation and Intellectual Property website. It is due to report to the World Health Assembly in 2012 as one part of WHO's actions under the global strategy and plan of action on public health, innovation and intellectual property.

#### 11. Is this just about people misusing antibiotics?

> Certainly, misuse of antibiotics is part of the problem – but drug resistance is much broader than that. Because drug resistance is a natural process, all microorganisms could eventually develop resistance to the medicines used to treat them. However, implementation of national policies and rational use of medicines by providers and patients, combined with infection control, can help considerably in slowing down the development and spread of resistance.

#### 12. What has WHO done about this issue in the past?

> WHO has been working to address drug resistance for many years and established successful mechanisms and programmes. For example, today, there are surveillance systems monitoring the effectiveness of medicines used to treat Tuberculosis (TB), malaria, HIV and gonorrhoea, as well as antibiotics used in animals. WHO also has a longstanding programme on rational use of essential medicines and drug quality regulation. It has developed policy on infection control and has sponsored the Patient Safety Alliance. The world now needs to move forward and implement the policy package that has been developed.

#### 13. Is this something new? Why is WHO talking about drug resistance now?

> Drug resistance is not new; it has been emerging since the discovery of the first antimicrobial drug. However, drug resistance keeps emerging and spreading rapidly. There is also a shortage of new antimicrobial drugs being developed to treat resistant microorganisms. WHO has now developed a package of policies that governments can put in place to tackle drug resistance. It is now essential for the world to work together and speed up the response to this problem.

#### 14. What is the cost of drug resistance?

> There is no global data for the cost of resistance. However, we do have good evidence from Europe and from the United States. In the European Union, 25,000 people die each year as a result of infection by multidrug resistant bacteria, at an estimated cost to healthcare systems of €1.5 billion per year. In the US, medical costs attributed to drug resistant infections are estimated at more than \$20 billion each year, with more than eight million additional days spent in hospitals as a result. The total cost to society amounts to more than \$35 billion a year.

### 15. Which countries are doing well in responding to drug resistance and which are not doing so well? Is anyone to blame?

> Drug resistance is a global public health issue; resistant organisms have arisen in many countries. Even countries with strong health systems face difficulties in controlling their spread. It is essential that countries set up strategies for prevention and control, including improved surveillance for resistance, rational antibiotic use in humans and animals, strengthening national drug regulatory authorities, and strengthening infection prevention and control in healthcare. Successful control of multidrug-resistant microorganisms has been documented in many countries, and the existing and well-known prevention and control measures can effectively reduce generation and spread of multi-drug resistant organisms if rigorously and systematically implemented.

#### 16. Is surveillance failing globally - why do we know so little?

> There have been major improvements in surveillance for some specific diseases. In Multidrug-resistant TB, for example, surveillance has been carried out in 114 countries and is supported by a network of laboratories.

There are still major gaps. This includes in expanding surveillance of hospital-acquired infections. Latin America has shown what can be done with limited resources. Many European countries through the European Centre for Disease Control (ECDC) are providing a powerful model that WHO is helping the rest of Europe to adapt and pursue. In the Eastern Mediterranean Region, Asia and Africa, nascent surveillance networks need to be revived and funded.