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DEFUSING THE BUG BOMB: LEGAL STRATEGIES TO COMBAT ANTIBIOTIC RESISTANT INFECTIONS

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I. INTRODUCTION

Antibiotics are truly a miraculous class of drugs¹ that have saved many lives.² With the development of antibiotics, certain diseases that were once considered death sentences are now simple infections that are easy to cure and control.³ Although many other classes of drugs were developed in the 20th century to fight microbial infections, none have proven as successful as antibiotics.⁴ The success of antibiotics is, however, leading to over-prescription and use of these drugs.⁵

The overuse of antibiotics has created a potential public health menace—the growth of microbial infections resistant to them.⁶ Antibiotic

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1. In describing the drugs' consequential importance, U.S. Surgeon General William H. Stewart once said, "[t]he time has come to close the book on infectious diseases." William Sage & David Hyman, *Combating Antimicrobial Resistance: Regulatory Strategies and Institutional Capacity*, 84 TUL. L. REV. 781, 784 (2010).

2. See Cory Fox, *Resisting Antibiotic Resistance: Legal Strategies To Maintain Man's Dominion Over Microbes*, 12 HOUS. J. HEALTH L. & POL'Y 35, 37 (2011) (discussing how antibiotics have been some of the most important and successful drugs in the treatment of disease).

3. Sage & Hyman, *supra* note 1, at 783 (noting that the rise of antibiotics eliminated once common causes of death, such as pneumonia and puerperal fever).

4. See, e.g., Fox, *supra* note 2, at 37 (stating that penicillin is one of the most successful treatments ever developed by mankind).

5. Sage & Hyman, *supra* note 1 (stating that persistent misuse and overuse of antibiotics is creating antibiotic resistance).

6. *Id.*

resistance stems from many causes that include the use of antibiotics in animal feed,⁷ medical practitioners' over-prescription, the general public's misuse of the drugs, and the failure to develop new antibiotics.⁸ This has led to the development of so called "super bugs" that are often immune to first line antibiotic therapies, such as penicillin, and to more powerful, broad-spectrum treatments.⁹

The Center for Disease Control ("CDC") has recognized this threat to public health.¹⁰ In a recent interview, the director of the CDC, Thomas R. Frieden, stated that "without urgent action now, more patients will be thrust back to a time before we had effective drugs."¹¹ The CDC highlights the extent of the problem, approximating that, as a "very conservative estimate," nearly two million Americans are infected each year with antibiotic resistant infections¹² and that 23 thousand Americans die as a result of such infections.¹³ The World Health Organization ("WHO") estimates that antibiotic resistant infections cost the U.S. health system between 20–35 million dollars.¹⁴ Steve Solomon, the director of antimicrobial resistance for the CDC, stated: "[w]e need to act now. We do not have antibiotics in the pipeline that are going to be available soon enough to address those problems."¹⁵

7. U.S. DEP'T OF HEALTH & HUMAN SERV., CTR. FOR DISEASE CONTROL & PREVENTION, ANTIBIOTIC RESISTANT THREATS IN THE UNITED STATES 11 (2013); *see also* Recommendations for Drug Sponsors for Voluntarily Aligning Product Use Conditions with GFI 209, 77 Fed. Reg. 22,327 (2012) (stating the FDA's concern in the use of antibiotics in animal feed, and providing guidance on the use of antibiotics in it).

8. *See Growing Antibiotic Resistance*, WASH. POST (Sept. 16, 2013, 8:12 PM), http://www.washingtonpost.com/national/health-science/growing-antibiotic-resistance/2013/09/16/b61ac100-1f2d-11e3-8459-657e0c72fec8_graphic.html (noting that the lack of development of new antibiotics and their over-prescription by doctors).

9. *See* CTR. FOR DISEASE CONTROL & PREVENTION, *supra* note 7, at 5 (discussing how antibiotic resistant infections are common, and that many first and second line antibiotics are on the verge of becoming ineffective treatments against them).

10. *Id.*

11. Brady Dennis & Brian Vastag, *Drug-Resistant Bacteria Pose Potential Catastrophe*, CDC Warns, WASH. POST (Sept. 16, 2013), http://www.washingtonpost.com/national/health-science/drug-resistant-bacteria-pose-potential-catastrophe-cdc-warns/2013/09/16/4cd2d482-1ed6-11e3-b7d1-7153ad47b549_story.html.

12. *Id.*

13. CTR. FOR DISEASE CONTROL & PREVENTION, *supra* note 7, at 6.

14. Press Release, Exec. Office of the President, Office of Sci. & Tech. Policy, PCAST Releases New Report on Combating Antibiotic Resistance (Sept. 18, 2014, 2:00 PM) (on file with author), *available at* <http://www.whitehouse.gov/blog/2014/09/18/pcast-releases-new-report-combating-antibiotic-resistance>.

15. Dennis & Vastag, *supra* note 11.

The costs of antibiotic resistant infections to human life and the economy are high, but are potentially avoidable with prompt action.¹⁶ If we are going to “defuse the bug bomb” and address the problem of antibiotic resistant infections, we need to take action to limit the use of current drugs and to develop new antibiotics.¹⁷ Congress has not adequately addressed this problem; while several bills have been introduced in Congress to address antibiotic resistant infections,¹⁸ these bills failed to address the real cause of superbugs. Instead, these bills focused on the use of antibiotics in livestock, and in any event, failed to become laws.¹⁹ Although the use of antibiotics in the agricultural industry is problematic, the CDC does not consider antibiotic use in livestock as the primary source of antibiotic resistant infections that threaten humans.²⁰ Rather, the CDC considers the primary source of antibiotic resistant infections in humans to come from our overuse of antibiotics and the failure to develop new antibiotics.²¹ In the words of the director of the CDC, “[t]he most resistant organisms in hospitals are emerging in those settings because of poor anti-microbial stewardship among humans.”²² Thus, this Article focuses on legal strategies both to control the use of antibiotics, and to develop antibiotic drug therapies to halt the spread of antibiotic resistant infections from person to person.

II. LEGAL STRATEGIES TO COMBAT ANTIBIOTIC RESISTANCE

Since congressional action has failed to address the impending public health crisis²³ that the CDC has identified,²⁴ the executive branch should

16. *See id.* (stating that concerted and prompt effort is needed by the nation to combat antibiotic resistance).

17. *See* CTR. FOR DISEASE CONTROL & PREVENTION, *supra* note 7, at 12 (discussing the need for aggressive action to combat antibiotic resistance).

18. *See, e.g.*, Strategies to Address Antimicrobial Resistance Act, H.R. 3697, 110th Cong. (2007) (seeking to fund data collection and awareness programs to fight the spread of antibiotic resistant infections) [hereinafter *Proposed Bill*]; *see also* Preservation of Antibiotics for Medical Treatment Act, H.R. 2400, 111th Cong. (2009) (seeking to take drastic actions to combat antibiotic resistant infections by banning the use of antibiotics in livestock feed, and creating tough approval standards for the use of new antibiotics on animals) [hereinafter *Proposed Bill*].

19. *See Proposed Bills, supra* note 18; *cf.* CTR. FOR DISEASE CONTROL & PREVENTION, *supra* note 7 (stating that human overuse in the medical context is the major cause of the development of antibiotic resistance).

20. CTR. FOR DISEASE CONTROL & PREVENTION, *supra* note 7; *see also* Dennis & Vastag, *supra* note 11 (stating that the major factor leading to antibiotic resistance is the overuse of the drug).

21. CTR. FOR DISEASE CONTROL & PREVENTION, *supra* note 7, at 11–12.

22. Dennis & Vastag, *supra* note 11.

23. *See Proposed Bills, supra* note 18 and accompanying text.

24. CTR. FOR DISEASE CONTROL & PREVENTION, *supra* note 7.

work within the existing legal framework to address super bugs. Within the existing legal framework, it is possible for the executive branch to take various actions that promote better stewardship of antibiotics through direct government regulation and the development of new classes of antibiotic drug therapies.²⁵

Through various statutes, the executive branch has the capacity to expediently address the issues of overuse of antibiotics and the failure to develop new drugs.²⁶ For example, the federal government could incorporate antibiotics into the Controlled Substances Act of 1970 (“CSA”).²⁷ While it is possible and desirable to control antibiotics domestically through the normal scheduling process in the CSA,²⁸ there is a potentially faster route. Another possible avenue to address this problem is to incorporate the control of antibiotics into an executive agreement.²⁹ Since the problem of antibiotic resistance is an international problem, this kind of agreement might be a more effective way to control the supply of current drugs on the market than through purely domestic control.³⁰

In addition to controlling the overuse of antibiotics, the government can take steps to promote the development of new antibiotics. The federal government can use various governmental programs that are intended to promote the development and stockpile of prophylactics to also counter potential public health emergencies in encouraging the development of antibiotics.³¹ For example, the federal government could use Project BioShield (a program originally intended to subsidize the development of new drugs to counter chemical, biological, nuclear, and radiological threats) to subsidize the development of new antibiotics.³² Further, the federal

25. See Combating Antibiotic Resistance, Executive Order 13676, 79 Fed. Reg. 56,931 (Sept. 23, 2014) (ordering various executive agencies to use all of the authority at their disposal to combat antibiotic resistance).

26. See *id.* (ordering executive agencies to use all available legal means at their disposal to combat antibiotic resistance).

27. 21 U.S.C. § 801 (2012).

28. See 21 U.S.C. § 811 (2012) (stating the authorities of various executive agencies and the scheduling process under the CSA).

29. See *Dames and Moore v. Regan*, 453 U.S. 654, 688 (1981) (holding that when Congress fails to act in an important foreign policy matter, the President has the authority to act).

30. See Editorial Board, *Antibiotic Resistance is a Huge Threat to Human Health*, WASH. POST (May 5, 2014), http://www.washingtonpost.com/opinions/antibiotic-resistance-is-a-huge-threat-to-human-health/2014/05/05/96b0279e-d23b-11e3-937f-d3026234b51c_story.html

(discussing the global reach of antibiotic resistance and how it is a large threat to the world’s public health); see also Combating Antibiotic Resistance, Executive Order 13676, 79 Fed. Reg. 56,931 (Sept. 23, 2014).

31. Project BioShield Act of 2004, 42 U.S.C. § 201 (2012).

32. Press Release, George Bush, President of the United States, Remarks at the Rose Garden at the Signing of S.15-Project BioShield Act of 2004 (July 21, 2004, 9:43 AM) (on file with

government could spur demand for new antibiotics by committing to purchase the newly developed drugs for the Strategic National Stockpile (“SNS”), a national stockpile of prophylactic countermeasures that would be released in the event of a public health crisis.³³ Once the federal government has placed antibiotics in Project BioShield and a company has contracted to develop them, the government could prioritize the development of new antibiotics that can treat superbugs pursuant to the Defense Production Act of 1950, which allows the President to order companies to give priority to government contracts that are needed to promote the national defense.³⁴ Lastly, the President could acquire the authority to prevent the spread of antibiotic resistant infections through the incorporation of superbugs into Executive Order 13295,³⁵ which enumerates the President’s quarantine authority. Taken together, use of these various legal options will limit and control the use of existing antibiotics, inhibit the spread of superbugs, and create a more viable antibiotic marketplace that encourages the development of novel therapies. The purpose of this Article is to briefly review and discuss the legality and feasibility of each of these avenues of executive action.

A. *Use of the Controlled Substances Act (“CSA”) to Limit the Overuse of Existing Antibiotics*

The CDC and WHO have stated that in order to control the spread of antibiotic resistant infections and maintain the effectiveness of antibiotics, it is important to limit their use.³⁶ Under existing federal law, the CSA is a primary means of controlling the supply of drugs.³⁷ The CSA allows the federal government to control the uses of certain drugs and even eliminate classes of drugs from the market.³⁸ As a result, the CSA can serve as a principal means of controlling drug over-prescription by adding disincentives to prescribing drugs when it is not appropriate to do so (for

author), *available* at <http://georgewbush-whitehouse.archives.gov/news/releases/2004/07/20040721-2.html>.

33. 42 U.S.C. § 247d-6b (2012).

34. 50 U.S.C. app. § 2071 (2012).

35. Revised List of Quarantinable Diseases, Executive Order 13674, 79 Fed. Reg. 45,671 (Aug. 6, 2014).

36. CTR. FOR DISEASE CONTROL & PREVENTION, *supra* note 7, at 11–12; *see also* Dennis & Vastag, *supra* note 11 (stating that the CDC would like to eliminate the unnecessary use of antibiotics in order to promote their continued effectiveness).

37. *See* 21 U.S.C. § 811 (2012) (granting the Attorney General authority to regulate and control substances that meet the requirements of the CSA).

38. 21 U.S.C. § 812 (2012); *see also* United States v. Oakland Cannabis Buyers’ Coop., 532 U.S. 483, 491 (2001) (noting how the CSA eliminates all uses of marijuana from the market except for uses within a government approved research project).

example, the CSA could attach various penalties to the over-prescription of antibiotics).³⁹

The CSA grants broad discretionary authority to the Attorney General (“AG”) and the Secretary of Health and Human Services (“Secretary”) to schedule drugs.⁴⁰ Under the CSA, the Secretary and the AG divide the scheduling authority.⁴¹ The AG is responsible for promulgating rules relating only to the registration and control of the “efficient execution of his functions” under the statute.⁴² The Secretary is responsible for making medical judgments and scientific determinations so that the federal government can then schedule a drug.⁴³ Under the CSA, the Secretary must make the necessary scientific and medical determinations before the AG can exercise his authority.⁴⁴ The scheduling process takes between six to twelve months;⁴⁵ scheduling can occur immediately, however, under the temporary authority of the AG.⁴⁶ Further, the AG can delegate his temporary scheduling authority to the Secretary.⁴⁷ As a result, the AG can immediately schedule antibiotics on a temporary basis, or the AG can delegate such authority to the Secretary.⁴⁸

The normal scheduling process requires the AG or the Drug Enforcement Administration (“DEA”)—the agency with the AG’s delegated authority—to consider seven factors before scheduling is authorized: (1) the actual or potential abuse of the drug; (2) the scientific evidence of its pharmacological effect; (3) the state of current scientific knowledge; (4) the history and current pattern of abuse of the drug; (5) the scope, duration, and significance of the abuse; (6) the risks to the public

39. BRIAN YEH, CONG. RESEARCH SERV., RL30722, DRUG OFFENSES: MAXIMUM FINES AND TERMS OF IMPRISONMENT FOR VIOLATIONS OF THE FEDERAL CONTROLLED SUBSTANCES ACT AND RELATED LAWS 3 (2012) (stating that the punishment for a first-time violation of the CSA for a schedule V drug ranges from a \$100,000–250,000 fine to up to 1 year in prison).

40. 21 U.S.C. § 811(a) (2012); *see also* *Touby v. U.S.*, 500 U.S. 160, 167 (1991) (holding that the broad discretionary authority granted to the AG through the CSA is not a violation of the non-delegation doctrine).

41. *Gonzales v. Oregon*, 546 U.S. 243, 265 (2006).

42. *Id.* at 259.

43. *Id.* at 265.

44. *Touby*, 500 U.S. at 162 (“A substance cannot be scheduled if the Secretary recommends against it.”).

45. *Id.* at 163 (“From the time when law enforcement identify a dangerous new drug, it typically takes 6 to 12 months to add it to one of the schedules.”).

46. *Id.* (quoting 21 U.S.C. § 811(h) (2012)) (“Congress in 1984 amended the Act to create an expedited procedure by which the Attorney General can schedule a substance on a temporary basis when doing so is ‘necessary to avoid an imminent hazard to public safety.’”).

47. *Id.* at 169 (discussing how the court has interpreted 21 U.S.C. § 501(a) to permit the delegation of any function vested in the AG unless a specific limit on that delegation appears elsewhere in the statute).

48. *Id.*

health; and (7) the psychic or physiological dependence liability.⁴⁹ The CSA mandates that the Secretary make any scientific findings before the AG can exercise his authority to schedule a drug.⁵⁰ Since the CDC is part of Health and Human Services (“HHS”), and therefore under the Secretary’s authority, the CDC has already reached numerous findings on the effects and dangers of the misuse of antibiotics.⁵¹ Therefore, the key to scheduling antibiotics under the CSA is for the Secretary to use this prior work to establish scientific findings that such misuse constitutes a threat to public health, and that control of the drug is justified.⁵²

1. Antibiotics meet the statutory requirements for scheduling

Antibiotics should qualify under most of the CSA’s various scheduling requirements. The CDC reports that antibiotics are the most commonly prescribed drugs and that up to 50% of all antibiotics prescribed are unnecessary.⁵³ Vicky Fraser, a member of the Infectious Diseases Society of America’s antimicrobial resistance committee, states that, “[o]ften when people are sick with viral infections, they want an antibiotic. . . . There is a misperception that antibiotics help everything, even viral infections.”⁵⁴ These misperceptions have led to the actual abuse of the drug,⁵⁵ and will lead to continued misuse without further controls.⁵⁶ There is little doubt that the misuse of antibiotics has substantially led to the rise of antibiotic resistant infections,⁵⁷ and that this constitutes an actual abuse of the drug with widespread misuse.⁵⁸ The current pattern of abuse occurs because of a multitude of factors, one of which is that “[o]ften people use antibiotics because they’re worried” and “[t]here’s pressure . . . to feel like they are doing something.”⁵⁹

49. 21 U.S.C. § 811(c)(1)–(7).

50. *Touby*, 500 U.S. at 162.

51. CTR. FOR DISEASE CONTROL & PREVENTION, *supra* note 7 (discussing the medical and economic harms that antibiotic resistant infections cause).

52. *See* 21 U.S.C. § 811(c)(6) (2012) (noting that the danger of the drug to the public health is a factor that should be taken into account when making scheduling decisions).

53. CTR. FOR DISEASE CONTROL & PREVENTION, *supra* note 7.

54. Dennis & Vastag, *supra* note 11.

55. CTR. FOR DISEASE CONTROL & PREVENTION, *supra* note 7.

56. *Id.* at 12 (“Bacteria will inevitably find ways of resisting the antibiotics we develop, which is why aggressive action is needed now to keep new resistance from developing and to prevent the resistance that already exists from spreading.”).

57. *Id.* at 11.

58. *See* 21 U.S.C. § 811 (2012) (noting that a drug with widespread misuse is an important factor when scheduling a drug).

59. Dennis & Vastag, *supra* note 11.

The widespread misuse of these drugs constitutes a public health threat because it leads to the development of superbugs.⁶⁰ More and more pathogens are becoming resistant to antibiotics and are becoming increasingly deadly.⁶¹ A prime example of such a pathogen is Carbapenem-resistant Enterobacteriaceae (“CRE”).⁶² According to the CDC, CRE has become resistant to almost all of the antibiotics currently available.⁶³ The disease results in roughly 600 deaths per year, and half of all bloodstream infections caused by CRE result in death.⁶⁴ Many in the medical profession refer to CRE as the “nightmare bacteria.”⁶⁵ Cases of CRE were documented throughout the country in hospitals, and even resulted in the deaths of seven people under the care of the prestigious National Institutes of Health (“NIH”).⁶⁶ The rise of resistant infections is connected to both the use of antibiotics when they are not needed, and when doctors prescribe antibiotics to meet the emotional demands of patients.⁶⁷ The abuse of antibiotics for psychic reasons is, in part, responsible for deaths from CRE and other antibiotic resistant infections.⁶⁸ The aggregation of individual abuses of antibiotics leads to the rise of resistant infections and pose a great threat to public health.⁶⁹ Antibiotics thereby satisfy the “public health” prong for scheduling.⁷⁰

There is only one statutory requirement that poses a potential problem for scheduling antibiotics: the drug’s psychic or physiological dependence liability.⁷¹ There is little, if any, risk for the development of physiological dependence on antibiotics;⁷² there is some risk, however, for an emotional

60. CTR. FOR DISEASE CONTROL & PREVENTION, *supra* note 7, at 28 (noting that the misuse of antibiotics overtime has lead to an increasing number of antibiotic resistant infections).

61. *See id.* at 15–17 (listing the various drug resistant infections).

62. *Id.* at 53–54.

63. *Id.*

64. *Id.*

65. Dennis & Vastag, *supra* note 11.

66. *Id.*

67. *See id.* (discussing the over-prescription of antibiotics and connecting their over-prescription to meeting the psychic demands of patients); *see also* CTR. FOR DISEASE CONTROL & PREVENTION, *supra* note 7, at 28 (noting that shortly after the development of penicillin, antibiotic resistance began to occur).

68. *See* CTR. FOR DISEASE CONTROL & PREVENTION, *supra* note 7, at 14 (demonstrating the process by which antibiotic resistance develops).

69. *Id.* at 41 (discussing how whenever antibiotics are used, it can lead to the development of antibiotic resistance and how this is especially problematic when antibiotic are misused are improperly used).

70. *See* 21 U.S.C. § 811 (2012) (providing that public health is a factor in the determination of whether a drug should be scheduled under the Act).

71. § 811(c)(7).

72. *See* CTR. FOR DISEASE CONTROL & PREVENTION, *supra* note 7, at 25 (discussing how antibiotics are generally safe drugs to use); *see also* *Using Antibiotics Wisely*, WEBMD, <http://www.webmd.com/a-to-z-guides/using-antibiotics-wisely-topic-overview> (last updated Mar.

dependence on the drug.⁷³ As previously noted, a large amount of the overuse of antibiotics comes from patients' misuse.⁷⁴

There is some evidence that the misuse of antibiotics is in part due to many individuals' need to feel like they are doing something to treat themselves.⁷⁵ Patients often seek these drugs—even when they have a viral infection, which is an infection that antibiotics will not treat.⁷⁶ Thus, since there is evidence that individuals use antibiotics for improper emotional purposes, antibiotics should qualify for scheduling under the CSA.⁷⁷ Further, the use of antibiotics for psychic purposes can lead to actual physical harm.⁷⁸ Antibiotics are responsible for one out of every five emergency room visits for adverse drug effects.⁷⁹ Among the most prevalent adverse reactions are those caused by allergic reactions as well as the development of *Clostridium difficile* (“*C. difficile*”).⁸⁰ *C. difficile* is a bacteria that can lead to a deadly diarrhea, which can develop from needlessly taking antibiotics.⁸¹ The amount of hospitalizations for adverse reactions to the misuse of antibiotics for psychic purposes alone warrants scheduling in its own right.⁸² The harms that directly result from misuse,⁸³ however, coupled with the indirect harms that flow from the development of resistant infections⁸⁴ create a strong argument for the AG and the Secretary to schedule antibiotics.

10, 2013) (noting the list of side effects from antibiotics and how physical dependency is not one of them).

73. See Dennis & Vastag, *supra* note 11 (discussing how people take antibiotics out of a sense of worry that is developed from various social pressures).

74. CTR. FOR DISEASE CONTROL & PREVENTION, *supra* note 7.

75. See, e.g., *The Spread of Superbugs*, THE ECONOMIST (Mar. 31, 2011), <http://www.economist.com/node/18483671> (discussing how antibiotics are misused by hypochondriacs).

76. See CTR. FOR DISEASE CONTROL & PREVENTION, *supra* note 7, at 34 (noting the demands of patients for antibiotics for the purpose of treating viral infections).

77. See 21 U.S.C. § 811(c)(7) (2012) (listing the factors that should be taken into when making a scheduling determination).

78. See CTR. FOR DISEASE CONTROL & PREVENTION, *supra* note 7, at 25 (stating the physical harms that can result from the misuse of antibiotics).

79. *Id.*

80. *Id.*

81. *Id.*

82. See *id.* at 26 (noting the 14,000 annual deaths as a result of *C. difficile*); cf. 21 U.S.C. § 811(c)(6) (2012) (stating that the threat to public health is an important factor in making scheduling decisions).

83. CTR. FOR DISEASE CONTROL & PREVENTION, *supra* note 7, at 25.

84. *Id.* at 11.

2. *Antibiotics should be controlled as a schedule V drug*

The CSA establishes a five-tiered “scheduling” program where drugs are placed into schedules ranked between I–V.⁸⁵ Schedule I is the most restrictive, while schedule V is the least restrictive.⁸⁶ Drugs in schedule I carry heavy criminal penalties and the drugs are banned for any purpose other than a government funded research project.⁸⁷ Drugs scheduled in classes II through V have “legitimate medical purposes,” and any registered doctor can prescribe these drugs.⁸⁸ Drugs prescribed under schedules II through V must be used “for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice.”⁸⁹ In *United States v. Oakland Cannabis Buyers Co-op*, the Court found that Congress determined that there was no legitimate medical purpose for schedule I drugs, and that the only legitimate usage of them was for government approved research.⁹⁰ Antibiotics should not be classified as a schedule I drug because they have significant medical benefits.⁹¹

The best category fit for antibiotics is schedule V. In order to classify a drug under schedule V, the following must apply: (1) the drug must have a low potential for abuse relative to the drugs in schedule IV; (2) the drug must have a currently accepted medical use in the U.S.; and (3) abuse of the drug may lead to limited physiological or psychic dependence.⁹² Antibiotics satisfy these statutory requirements, and can be classified as a schedule V drug. First, antibiotics have a low potential for abuse compared to every other schedule.⁹³ Second, antibiotics have a clearly accepted medical use in the U.S.—to treat bacterial infections.⁹⁴ Third, antibiotics are sometimes

85. 21 U.S.C. § 812(a) (2012).

86. 21 U.S.C. § 841 (2012); *see also* BRIAN YEH, *supra* note 39.

87. § 812; *see also* *United States v. Oakland Cannabis Buyers Coop.*, 532 U.S. 483, 490 (2001) (holding that all drugs classified as schedule I are not subject to a common law medical necessity defense).

88. § 812(b)(2)–(5)(B).

89. 21 C.F.R. § 1306.04(a) (2005).

90. 532 U.S. 483, 491 (2001) (“In the case of the Controlled Substances Act, the statute reflects a determination [by Congress] that marijuana has no medical benefits worthy of an exception (outside the confines of a Government-approved research project).”).

91. *See* NAT’L INST. OF HEALTH, *Antibiotics*, MEDLINEPLUS, <http://www.nlm.nih.gov/medlineplus/antibiotics.html> (last updated Dec. 23, 2014) (discussing the various medical benefits of antibiotics).

92. § 812(b)(5).

93. *See* § 812 (noting that the drugs that are already contained within schedule IV and antibiotics have a smaller psychic or physical dependence liability than schedule IV drugs); *see also* Sage & Hyman, *supra* note 1, at 816 (discussing the use of the CSA to schedule any newly developed antibiotics in order to defend their efficacy).

94. NAT’L INST. OF HEALTH, *supra* note 91.

prescribed for psychic reasons.⁹⁵ Antibiotics are the most-prescribed drugs in the world and are often incorrectly prescribed.⁹⁶ Therefore, there is an increased potential for abuse because of the ubiquity and ease of the availability of antibiotics.⁹⁷ For these reasons, antibiotics should be controlled as a schedule V drug under the CSA.

The scheduling of antibiotics would also put physicians on notice that they need to better control their prescription of antibiotics.⁹⁸ In *United States v. Moore*,⁹⁹ the U.S. Supreme Court held that being a registered doctor does not give doctors blanket authorization to distribute or dispense controlled substances.¹⁰⁰ The Court ruled that since the CSA mandates that doctors must comply with the plain language of the statute and its implementing regulations, doctors must abide by the restrictions of the CSA or they will face fines and other possible penalties.¹⁰¹

The benefit of scheduling antibiotics as a class V drug is that it will result in the least amount of restrictions while also providing patients with a vital life saving drug.¹⁰² Additionally, scheduling limits doctors' prescription of the drug to medical necessity while also punishing negligent behavior.¹⁰³ If antibiotics are so scheduled, then doctors will not be subject to penalties when they are properly administering antibiotics.¹⁰⁴ To avoid penalties and other risks, doctors would only need to do what they are

95. See Dennis & Vastag, *supra* note 11 (discussing how people want antibiotics in order to feel like they are being treated).

96. CTR. FOR DISEASE CONTROL & PREVENTION, *supra* note 7.

97. See Howard Markel, *No Prescription for Antibiotics? No Problem*, N.Y. TIMES (Nov. 12, 2002), <http://www.nytimes.com/2002/11/12/health/no-prescription-for-antibiotics-no-problem.html> (discussing how easy it is to get antibiotics in the U.S. without a prescription).

98. See 21 U.S.C. § 801 (2012) (stating that many controlled substances have a legitimate medical purpose, but that they also pose a detrimental effect to the welfare of the American people, and that it is important for the federal government to regulate access to them); see also Sage & Hyman, *supra* note 1, at 816 (discussing how the CSA could be used to control the supply of antibiotics).

99. 423 U.S. 122 (1975).

100. *Id.* at 124 (holding that doctors can be prosecuted for violations of the CSA when their conduct falls outside the course of professional practice).

101. *Id.* at 131 (ruling that the CSA only exempts lawful acts from prosecution, and that doctors are not exempt from the requirements of the statute).

102. See 21 U.S.C. § 812 (2012) (stating that schedule V drugs have a "currently accepted medical use in the United States"); see also BRIAN YEH, CONG. RESEARCH SERV., RL34635, THE CONTROLLED SUBSTANCES ACT: REGULATORY REQUIREMENTS (2012).

103. BRIAN YEH, *supra* note 39 (noting that the punishment for violating the CSA for a schedule V drug ranges from a fine from \$100,000–250,000 or up to 1 year in prison for the first violation); see also *Moore*, 423 U.S. at 133 (stating that only the lawful acts of registrants are exempted from prosecution, which include prescribing antibiotics for legitimate medical purposes).

104. *Moore*, 423 U.S. at 140 (holding that the statute was designed to limit the dispensing authority of controlled substances to activities within the doctor's professional practice).

already supposed to do: prescribe antibiotics when it is medically necessary to do so.¹⁰⁵

3. *The decision to schedule antibiotics should be upheld by the courts*

The CSA grants broad discretionary authority to the executive branch in determining whether or not a drug should be scheduled.¹⁰⁶ This authority, however, is not granted to one single department of the executive branch.¹⁰⁷ In order to schedule a drug, the Secretary must first make a scientific determination on its dangers.¹⁰⁸ If the Secretary makes a scientific determination on the health effects of the misuse of antibiotics, the CSA then authorizes the AG to schedule the drug.¹⁰⁹ The courts have generally given broad deference to the executive branch in the exercise of delegated discretionary authority.¹¹⁰ The broad deference afforded to the executive branch should mean that the court would use the findings of the Secretary and the AG to determine that the scheduling is not “arbitrary and capricious.”¹¹¹ In addition, the AG’s decision to schedule antibiotics is not likely to be considered an unlawful attempt to define the practice of medicine.¹¹² As a result, the courts will likely uphold the scientific findings of the secretary and the scheduling decision of the AG.

Under *Chevron v. Natural Res. Def. Council*,¹¹³ the Court will likely grant the executive branch broad deference in its scientific findings and subsequent decision to schedule antibiotics.¹¹⁴ In *Chevron*, the Court stated that the judiciary affords substantial deference to an administrative interpretation of an ambiguous statute.¹¹⁵ The primary issue then becomes

105. *Id.*

106. See 21 U.S.C. § 811 (2012) (stating the scheduling authority of various executive branch departments).

107. *Id.* (noting how the scheduling process is split between the AG and the Secretary, who are the heads of two different departments within the executive branch).

108. *Id.* § 811(b).

109. *Id.*

110. See *Chevron v. Natural Res. Def. Council*, 467 U.S. 837, 844 (1987) (stating that an administrative agency is generally given broad deference to interpret the statutory regimes they are entrusted to implement).

111. See 5 U.S.C. § 706 (2012) (stating the conditions by which agency action can be reviewed); see also 21 U.S.C. § 877 (2012) (stating that findings of fact by the AG are conclusive).

112. See, e.g., *Gonzales v. Raich*, 545 U.S. 1, 27 (2005) (upholding the validity of the CSA and stating that it is a valid regulatory regime that controls the use of substances with medical uses).

113. 467 U.S. 837, 844 (1987).

114. *Id.*; see also *Gonzales*, 545 U.S. at 27 (articulating the broad regulatory powers of the CSA).

115. 467 U.S. at 844.

whether the Secretary's scientific findings, when properly viewed through the broad deference doctrine afforded to executive decisions under *Chevron*, would be arbitrary and capricious.¹¹⁶ The CSA requires that the Secretary make the findings based upon substantial evidence.¹¹⁷ Under the CSA's standard, a court must consider whether "a reasonable mind might accept a particular evidentiary record as adequate to support a conclusion."¹¹⁸ The executive is not required to have absolute medical certainty in making its determinations, but rather only a legitimate basis to take action based on the current state of medical evidence.¹¹⁹ The medical community, including the WHO and the CDC, has developed substantial evidence of the negative effects of the overuse of antibiotics.¹²⁰ In addition, there is well-established evidence of the dramatic adverse public health effects as a result of the spread of antibiotic resistance.¹²¹ The CSA does not require absolute medical certainty in order for the Secretary to make a medical finding.¹²² As a result, the existing evidence on psychic dependence, even though not conclusive, could still permit scheduling when it is properly viewed as a public health statute.¹²³ Therefore, overwhelming evidence of the dangerous overuse and misuse of antibiotics by the public overshadows the relative uncertainty as to the potential liability for dependence on antibiotics.¹²⁴ Thus, when viewed in its totality, the courts will likely afford the medical record *Chevron* deference, and will likely deem scheduling of antibiotics lawful.¹²⁵

The CSA grants discretionary authority to the AG to decide which substances should be registered and controlled; the Secretary, however,

116. 5 U.S.C. § 706 (2012) (setting forth the arbitrary and capricious standard for agency action); 21 U.S.C. § 877 (2012).

117. *See Am. for Safe Access v. Drug Enforcement Admin.*, 706 F.3d 438, 450 (D.C. Cir. 2013) (stating that the CSA directs courts to review the agency's findings of substantial findings).

118. *Id.* (quoting *Dickinson v. Zurko*, 527 U.S. 150, 162 (1999)).

119. *See* 21 U.S.C. § 811 (2012) (stating that scheduling decisions must be made based on the current state of scientific understanding); *see also Am. for Safe Access*, 706 F.3d at 450 (applying a reasonable person standard to the adequacy of data used to make scientific findings).

120. CTR. FOR DISEASE CONTROL & PREVENTION, *supra* note 7 (discussing the various negative effects from the overuse of antibiotics).

121. *Id.*

122. *See Alliance for Cannabis Therapeutics v. Drug Enforcement Admin.*, 930 F.2d 936, 939 (1991) (stating that absolute medical certainty is not needed to meet the statutory requirements for scheduling).

123. 21 U.S.C. § 811(c)(6) (2012) (requiring the Secretary to determine what, if any, risk exists to the public health).

124. *See* CTR. FOR DISEASE CONTROL & PREVENTION, *supra* note 7 (noting the volume of evidence demonstrating that the overuse of antibiotics causes a threat to the public health).

125. *See, e.g., Am. for Safe Access v. Drug Enforcement Admin.*, 706 F.3d 438, 452 (D.C. Cir. 2013) (holding that the scientific determination that marijuana has no valid medical use, in spite of evidence to the contrary, was not an invalid finding by the agency).

cannot trigger this authority without appropriate medical findings.¹²⁶ In order for the AG to schedule a drug as arbitrary and capricious, the AG must do so without scientific findings from the Secretary, and the AG's actions must constitute an attempt to define the practice of medicine.¹²⁷ In *Gonzales v. Oregon*,¹²⁸ the Court ruled that the AG acted beyond his statutory authority when he used his rulemaking authority under the CSA because the AG's regulation sought to define the practice of medicine and was made without a scientific finding from the Secretary.¹²⁹ In *United States v. Moore*,¹³⁰ the Court granted the AG broad authority to criminalize improper drug dispensing practices that lead to the harm of patients.¹³¹ The Court, however, limited the authority of the AG to scheduling drugs when such action defines what constitutes the practice of medicine.¹³² Based on this rationale, the Court in *Oregon* found that the AG does not have the authority to promulgate regulations under the CSA that would criminalize the prescription of drugs to assist patient suicide.¹³³ The AG determined that the physician's purpose of dispensing of drugs for assisted suicides was not within the legitimate medical practice, and that this practice was unlawful under the CSA.¹³⁴ The Court stated that Congress delegated limited authority to the AG for creating regulations pursuant to the control of drugs. Under the CSA, "control" means "to add a drug or substance to a schedule."¹³⁵ The AG does not, however, have the authority to define which acts are within the practice of medicine.¹³⁶ Rather, the states have the authority to determine what constitutes the practice of medicine.¹³⁷ If the state deems an action as within the practice of medicine, the AG cannot then make a regulation that criminalizes the action under the CSA.¹³⁸

The scheduling of antibiotics under the CSA does not constitute an impermissible attempt to define the practice of medicine as articulated in

126. 21 U.S.C. § 811(b) (2012); see *Gonzales v. Oregon*, 546 U.S. 243, 265 (2006).

127. *Gonzales*, 546 U.S. at 264–65.

128. 546 U.S. 243 (2006).

129. *Id.* at 264–65.

130. 423 U.S. 122 (1975).

131. *Id.* at 124.

132. *Gonzales*, 546 U.S. at 261–62.

133. *Id.* at 261.

134. *Id.* at 254.

135. 21 U.S.C. § 802(5) (2009).

136. *Gonzales*, 546 U.S. at 272.

137. *Id.* at 270 (interpreting the CSA as relying upon state based definitions for the practice of medicine).

138. *Id.* at 262 (highlighting the efforts of Congress to refuse granting authority to the AG to define what constitutes the practice of medicine).

the *Oregon* decision.¹³⁹ First, in *Oregon*, the Court was faced with a situation where the state had affirmatively determined that physician-assisted suicide was within legitimate practice of medicine via a statute.¹⁴⁰ Currently, there is no affirmative statute allowing for the use of antibiotics for any reason other than treating bacterial infections.¹⁴¹ The scheduling of antibiotics only seeks to control the use of antibiotics in situations when it is not medically appropriate to do so.¹⁴² Second, unlike *Oregon*, the AG would be scheduling antibiotics only once the Secretary has made proper scientific findings.¹⁴³ Third, unlike *Oregon*, when scheduling antibiotics, the AG would not be seeking to define a specific act that is not within the legitimate exercise of the practice of medicine, but rather would seek to schedule a whole class of drugs in order to promote the public health.¹⁴⁴ By scheduling antibiotics under the CSA, the AG is only attempting to bar doctors from prescribing drugs when it is not medically required.¹⁴⁵ Such a requirement does not conflict with state law or a state's determination of what constitutes the practice of medicine.¹⁴⁶ In fact, scheduling serves to complement the state's definition of the practice of medicine by attaching penalties to actions that doctors should not be taking.¹⁴⁷ Thereby, the scheduling of antibiotics merely adds additional disincentives to actions that doctors should already not be taking.¹⁴⁸

139. See *Gonzales v. Raich*, 545 U.S. 1, 27 (2005) (noting the ability of the government to control the use of substances with legitimate medical uses under the CSA without constituting an impermissible attempt to define the practice of medicine).

140. OR. REV. STAT. § 127.800 (1999); see also *Gonzales*, 546 U.S. at 252.

141. See, e.g., VA. CODE ANN. § 54.1-3303 (2010) (stating that prescription drugs, including antibiotics, can only be issued for legitimate therapeutic reasons).

142. *United States v. Moore*, 443 U.S. 122, 131–32 (1975) (holding that lawful acts of doctors who are registered under the act are exempt from criminal liability).

143. *Gonzales*, 546 U.S. at 253–54 (noting that the AG's regulation of the use of drugs to assist patients in suicide was unlawful under the CSA because the AG failed to acquire a scientific finding from the Secretary).

144. See *Gonzales*, 545 U.S. at 27; see also 21 U.S.C. § 801 (1973) (discussing the purpose of the CSA).

145. *Moore*, 423 U.S. at 140–41 (1975) (stating that doctors can dispense drugs when it falls within his professional practice); see also *United States v. Kanner*, 603 F.3d 530, 535 (8th Cir. 2010) (upholding the ruling of *Moore* after the *Oregon* decision, ruling that distributing drugs outside the course of professional practice constitutes a criminal violation of the CSA).

146. *Moore*, 423 U.S. at 141; see also *Gonzales*, 545 U.S. at 24 (noting that the scheduling of drugs is not an attempt to define the practice of medicine, but rather a regulatory action to control the misuse of drugs with legitimate medical uses to protect the general welfare of the American people).

147. *Moore*, at 144 (“[The] implication is that physicians who go beyond approved practice remain subject to serious criminal penalties.”).

148. See, e.g., VA. CODE ANN. § 54.1-3303 (2010) (noting that under Virginia state law, the prescription of any drug without medical necessity is a criminal violation).

The plain language of the CSA and the *Oregon* decision itself grants broad authority to the Secretary to schedule drugs as long as the Secretary makes the necessary medical findings, and that the class of drugs can satisfy all of the statutory requirements for scheduling.¹⁴⁹ The *Oregon* decision does not bar the AG and the Secretary from exercising their broad discretionary authority to choose which drugs to schedule.¹⁵⁰ *Oregon* only bars the AG from defining what constitutes the practice of medicine when the states have already done so.¹⁵¹ As a result, the scheduling of antibiotics, if done according to the normal scheduling process, would likely be upheld as a valid exercise of statutory authority of the Secretary and the AG.

B. The Use of Executive Agreements to Control the Improper Use of Antibiotics

Antibiotics satisfy all of the statutory requirements for scheduling under the CSA; it may be more effective, however, to control antibiotics through international agreements.¹⁵² This makes sense because the problem of antibiotic resistant infections is not uniquely an American problem.¹⁵³ In recent reports, the CDC and WHO have stated that antibiotic resistance is a problem that does not recognize political boundaries and will likely require international cooperation to effectively combat.¹⁵⁴ An international agreement on the use of antibiotics could potentially provide more effective control of the spread of antibiotic resistant infections than scheduling would under purely domestic authority.¹⁵⁵ Coordinating U.S. efforts with other countries would likely reduce antibiotic resistant infections from entering American borders, and would reduce global misuse of antibiotics.¹⁵⁶ Moreover, the use of an international agreement to control antibiotics for the purposes of fighting antibiotic resistance and preventing a public health

149. *Gonzales v. Oregon*, 546 U.S. 243, 260 (2006).

150. *Id.*

151. *Id.* at 270 (stating that the CSA “piggybacks” off of state law and relies on it to define what falls within the legitimate practice of medicine).

152. *See Nat’l Org. for Reform of Marijuana Laws v. Drug Enforcement Agency*, 559 F.2d 735, 746 (D.C. Cir. 1977) (discussing the how the AG may schedule a drug in order to meet an international obligation without regard to the normal scheduling process).

153. *See* CTR. FOR DISEASE CONTROL & PREVENTION, *supra* note 7, at 27 (noting the lack of international surveillance systems); *see also* Dennis & Vastag, *supra* note 11.

154. CTR. FOR DISEASE CONTROL & PREVENTION, *supra* note 7; *see also* Dennis & Vastag, *supra* note 11 (discussing the international nature of antibiotic resistance and the particular importance of combating resistant infections); *see also* Combating Antibiotic Resistance, Executive Order 13676, 79 Fed. Reg. 56,931 (Sept. 23, 2014).

155. *See supra* note 152.

156. *See supra* note 152.

crisis can occur without any further congressional action.¹⁵⁷ Although the Constitution requires the President to ratify treaties with the advice and consent of two-thirds of the Senate,¹⁵⁸ an executive agreement (an agreement between the executive branch of the United States and the executive of a foreign country without the approval of the Senate)¹⁵⁹ can occur without such approval.¹⁶⁰ As a result, the agreement becomes a de facto treaty.¹⁶¹ In *Dames and Moores v. Regan*, the Court stated that when Congress acquiesces its responsibility to resolve important matters of foreign policy, the President can take action to resolve such matters.¹⁶² So far, Congress has acquiesced in regards to the issue of antibiotic resistant infections by failing to pass legislation¹⁶³ even in the face of warnings of the impending public health crisis from both domestic and international health authorities.¹⁶⁴ In these circumstances, the President could enter into an executive agreement with other countries to take measures to halt the spread of antibiotic resistant infections.

C. Project BioShield Could Provide a Basis to Spur New Antibiotic Development

The CSA provides for an effective means of controlling the use of existing antibiotics. Antibiotic stewardship alone, however, is not sufficient to halt the spread of antibiotic resistant infections; we must also develop new antibiotics.¹⁶⁵ The Project BioShield Act of 2004¹⁶⁶ (“Project BioShield”) was enacted in order to spur the development of

157. See *Dames & Moores v. Regan*, 453 U.S. 654, 688 (1981) (discussing the President’s authority to act in the international realm in the absence of congressional authorization).

158. U.S. CONST. art. II, § 2, cl. 2.

159. *Treaty vs. Executive Agreement*, Frequently Asked Questions, U.S. DEPARTMENT OF STATE, <http://www.state.gov/s/l/treaty/faqs/70133.htm> (last visited Dec. 28, 2014) (stating that the difference between an executive agreement and a treaty is that a treaty is done with the advice and consent of the Senate, while an executive agreement is an international agreement entered into solely through the constitutional authority of the President).

160. *United States v. Pink*, 315 US 203, 229–30 (1942).

161. See U.S. DEP’T OF STATE, 11 FOREIGN AFFAIRS MANUAL 723.2-2(C) AGREEMENTS PURSUANT TO THE CONSTITUTIONAL AUTHORITY OF THE PRESIDENT (2006) (discussing when an international agreement can be entered into based solely on the President’s constitutional powers without the advice and consent of the Senate).

162. 453 U.S. at 688.

163. *Proposed Bills*, *supra* note 18 and accompanying text.

164. Press Release, U.S. Dep’t of Health & Human Serv., Ctr. For Disease Control & Prevention (May 1, 2014) (on file with author), *available at* <http://www.cdc.gov/media/releases/2014/s0430-who-antibiotic-resistance.html>.

165. CTR. FOR DISEASE CONTROL & PREVENTION, *supra* note 7, at 44 (noting that bacterial infections will inevitably evolve and as a result, new antibiotics will need to be developed).

166. 42 U.S.C. § 247d-6a (2012).

countermeasures against chemical, biological, radiological, and nuclear (“CBRN”) threats.¹⁶⁷ The law was passed in the wake of 9/11 and the anthrax attacks.¹⁶⁸ These attacks created widespread fear in America, and highlighted the nation’s vulnerability to CBRN threats due to a lack of effective countermeasures.¹⁶⁹ While Project BioShield was passed with the intent of preventing and mitigating the effects of terrorist attacks,¹⁷⁰ the language of the statute does not limit the development of countermeasures for that purpose alone.¹⁷¹ Project BioShield authorizes the Secretary to grant research and development funds to “qualified countermeasures.”¹⁷² A “qualified countermeasure” is defined as any medical product that the Secretary deems necessary to treat any biological agent, including organisms that cause infectious disease that may cause a public health emergency affecting national security.¹⁷³

Project BioShield was developed because of the failures of the market system to produce countermeasures to CBRN threats.¹⁷⁴ As with the failure to produce countermeasures to CBRN threats, the market has also failed to develop new antibiotics to combat resistant infections.¹⁷⁵ The Secretary could use the broad discretionary authority granted to him under Project BioShield in order to deem novel antibiotics as “qualified countermeasure[s].”¹⁷⁶ The Secretary has substantial evidence showing that the public’s vulnerability to various resistant diseases is so dangerous to the public health that it threatens the nation’s security.¹⁷⁷ Placing antibiotics

167. Press Release, George Bush, President of the United States, Remarks at the Rose Garden at the Signing of S.15-Project BioShield Act of 2004 (July 21, 2004, 9:43 AM) (on file with author), *available at* <http://georgewbush-whitehouse.archives.gov/news/releases/2004/07/20040721-2.html> (discussing the reasons why Project BioShield was passed into law, and the policy goals of the legislation).

168. *Id.*

169. *Id.*

170. *Id.*

171. § 247d-6a(1) (noting that the Secretary’s authority extends to “qualified countermeasures,” which includes anything that may treat harm from a biological agent (including organisms that cause infectious diseases)).

172. § 247d-6a(a)(2)(A)(i).

173. *Id.*

174. FRANK GOTTRON, CONG. RESEARCH SERV., R41033, PROJECT BIOSHIELD: AUTHORITIES, APPROPRIATIONS, ACQUISITIONS, AND ISSUES FOR CONGRESS 1 (2011).

175. Fox, *supra* note 2, at 45–46 (stating that the lack of new antibiotics is largely because of market failures); *see also* INFECTIOUS DISEASE SOC’Y OF AM., BAD BUGS, NO DRUGS: AS ANTIBIOTICS DISCOVERY STAGNATES, A PUBLIC HEALTH CRISIS BREWS 16 (2004) (stating that the success of antibiotics in treating disease serves as a disincentive to drug producers to develop new antibiotics).

176. § 247d-6a(a)(2)(A)(i).

177. Combating Antibiotic Resistance, Executive Order 13676, 79 Fed. Reg. 56,931 (Sept. 23, 2014) (noting that the President has declared antibiotic resistance as a threat to national security and made this determination using evidence provided by the CDC).

under Project BioShield allows for the use of a five billion dollar fund to subsidize the development of new antibiotics, and in addition, Project BioShield provides a market guarantee for these products.¹⁷⁸ The government guarantees a market for any developed drugs by agreeing that any developed drug will be incorporated into the SNS.¹⁷⁹ The SNS is a stockpile of countermeasures that the government holds in reserve throughout the country in the event that there is a catastrophic public health emergency.¹⁸⁰ It is necessary to develop new antibiotics in order to ensure the continued effectiveness of current drugs, as well as to widen treatment options against resistant infection strains.¹⁸¹ Therefore, HHS should use its broad authority to incorporate antibiotics into the Project BioShield program.¹⁸² The inclusion of antibiotics into Project BioShield would recognize the growing threat that antibiotic resistant infections pose to the nation while also providing an important market incentive to private companies to develop new drugs.

Project BioShield grants the HHS Secretary (in concurrence with the Secretary of the Department of Homeland Security (“DHS”), and upon approval of the President) the authority to purchase a countermeasure up to eight years before the drug is developed and delivered.¹⁸³ In order to provide an additional incentive beyond the market guarantee, HHS is authorized to deliver up to half of the payment for the drug before it is even successfully developed.¹⁸⁴ The purpose of this provision is to subsidize the substantial amount of money needed in order to develop new drugs.¹⁸⁵ Many experts believe that it can cost up to one billion dollars to develop any given new prophylactic.¹⁸⁶ Incorporating antibiotics into the pool of drugs that the government seeks to develop through Project BioShield will likely result in the development of more powerful antibiotics that can effectively combat resistant infections. Moreover, placing antibiotics into Project BioShield will help overcome the lack of financial incentives to create new drugs in the current market.¹⁸⁷ The federal government can also

178. GOTTRON, *supra* note 174, at 5.

179. *Id.* at 2.

180. § 247d-6b(a).

181. Fox, *supra* note 2, at 61.

182. § 247d-6a (noting that the Secretary can use their authority to approve the development for any “qualified countermeasure”).

183. GOTTRON, *supra* note 174, at 2–3.

184. *Id.*

185. *Id.* at 1.

186. Matthew Herper, *The Truly Staggering Cost of Inventing New Drugs*, FORBES (Feb. 10, 2012, 7:41 AM), <http://www.forbes.com/sites/matthewherper/2012/02/10/the-truly-staggering-cost-of-inventing-new-drugs/> (stating that the cost to develop new drugs is around 1.3 billion dollars).

187. GOTTRON, *supra* note 174, at 3.

create a guaranteed market and provide advance funding in order to help subsidize high research and development costs, motivating drug companies to develop new drugs.¹⁸⁸

1. *Project BioShield allows the federal government to promote stewardship of newly developed antibiotics*

If new antibiotics are developed under Project BioShield, the major consumer of the drugs will be the federal government.¹⁸⁹ The government will have control over a major supply of the drug, and as a result, will be in a better position to promote stewardship over new antibiotics.¹⁹⁰ Although the drug will still be available to the general public for use when it is medically necessary, the government's control over the supply will make it more difficult for new drugs to be overused.¹⁹¹ The federal government's withholding of a large supply of the drug on the open market will help maintain a higher price for the drug, causing it to only be used when medically necessary.¹⁹² The prospect of a higher market price will further incentivize drug companies to develop new antibiotics.¹⁹³ The use of Project BioShield will not only lead to the development of new drugs, but will help control the supply of the drugs in a manner that promotes the long term effectiveness of antibiotics.¹⁹⁴

188. *Id.* (noting that the incentives of Project BioShield substantially reduces the risks of private investment by providing a guaranteed market and funds).

189. *See, e.g.,* Steve Sternberg, *U.S. Government Stockpiles New, Safer Smallpox Vaccine*, USA TODAY (May 25, 2010, 1:37 PM), http://usatoday30.usatoday.com/news/health/2010-05-25-smallpox25_ST_N.htm (discussing how the U.S. has stockpiled over 300 million doses of smallpox vaccine as part of the SNS, and demonstrating how the market guarantee can be an effective incentive for the production of new countermeasures).

190. *See* Fox, *supra* note 2, at 61 (stating that in order to combat antibiotic resistant infections, there must be effective drug stewardship, and new drugs must be developed).

191. *Id.* (noting that the market guarantee will cause a substantial portion of any produced antibiotic to be under direct government supervision in the SNS, and thereby not available for public consumption on the open market).

192. Sage & Hyman, *supra* note 1, at 814 (discussing how government stockpiling will reduce the supply of available drugs to the general public).

193. *See* Alexandra Sifferlin, *Why Reducing Antibiotic Resistance Is Harder Than It Seems*, TIME (Sep. 19, 2014), <http://time.com/3403542/combating-antibiotic-resistance/> (discussing the influence of price, and how federal incentives can be changed to increase prices of antibiotics and encourage development).

194. *See* 42 U.S.C. § 247d-6b (2012) (discussing the procurement process under Project BioShield as well as the stockpiling of drugs in the SNS, which controls the supply of newly developed drugs while also providing a market guarantee that encourages their development).

2. *Potential funding limitations of Project BioShield*

Like many federal government programs, Project BioShield is not without its flaws. The primary problem with Project BioShield is that Congress transferred many of the funds originally appropriated to the program to other parts of the government.¹⁹⁵ As a result, Project BioShield's funding stream to purchase drugs is not stable.¹⁹⁶ The instability in funding creates a disincentive to private companies seeking funds to develop drugs pursuant to the program.¹⁹⁷ The instability of funding is particularly problematic because the upfront costs of developing new drugs are extremely high.¹⁹⁸ While lack of steady funding could inhibit the prospect of developing new antibiotics under the program, it is not conclusive.¹⁹⁹ The market incentives currently in place (the SNS and prepayment programs in concert with normal market forces) create a powerful economic incentive for private corporations to actually develop new antibiotics that can overcome the flaws of Project BioShield.²⁰⁰ Unlike antibiotics, CBRN countermeasures can only be used in the event of a crisis and only have one true purchaser: the government.²⁰¹ New antibiotics are not limited to use only in the event of a crisis.²⁰² Rather, antibiotics have broader appeal and are more regularly used by the general public.²⁰³

195. GOTTRON, *supra* note 174, at 5 (discussing how funds have been transferred out of Project BioShield, creating an unstable funding source for prospective users of the program).

196. *Id.* (stating that funds have been rescinded and transferred out of Project BioShield, creating an unstable fund instead of the dedicated 5 billion dollar fund that was originally intended).

197. *Id.*

198. Herper, *supra* note 186 (stating that the cost of developing new drugs are extraordinarily high, and as a result, instability in funding sources creates additional risks that may serve as an additional disincentive to development of new antibiotics).

199. *See, e.g.*, Sternberg, *supra* note 189 (discussing how the U.S. has stockpiled over 300 million doses of smallpox vaccine as part of the SNS, and demonstrating how the SNS and the market guarantee can lead to large orders for products by the government, which serves as a substantial incentive for development).

200. *See, e.g.*, Sten Stovall, *EU Joins Widening Push to Find New Antibiotics*, WALL ST. JOURNAL (May 24, 2012, 8:41 AM), <http://online.wsj.com/news/articles/SB10001424052702304707604577423683954355876> (discussing how financial incentives and other government efforts can encourage drug companies to develop new antibiotics).

201. GOTTRON, *supra* note 174, at 11 (noting how the pharmaceutical market has failed to produce CBRN countermeasures and that the government provides a market guarantee for CBRN countermeasure development); *see also, e.g.*, Sternberg, *supra* note 189 (providing an example of how the government is the true purchaser of CBRN countermeasures).

202. NAT'L INST. OF HEALTH, *supra* note 91 (stating that antibiotics fight various bacterial infections).

203. Stovall, *supra* note 200 (discussing the importance of antibiotics to the practice of medicine and their widespread use and appeal).

Antibiotics do not have the problem of only having the government as its sole purchaser.²⁰⁴ Instead, antibiotics are an important prophylactic that the government wants to purchase, and are also medicines that the general public will use outside of a crisis situation.²⁰⁵ As a result, the development of new antibiotics under Project BioShield is far more likely to occur than CBRN countermeasures.²⁰⁶

D. Priority Development of New Antibiotics Through the Use of the Defense Production Act

Another legal tool in the President's arsenal to fight superbugs is to exercise his authority pursuant to the Defense Production Act of 1950 ("DPA"),²⁰⁷ where the President can order the priority performance of contracts with drug companies in order to develop new antibiotic therapies.²⁰⁸ The DPA grants the President legal authority to issue such an order when he deems it necessary for the national defense.²⁰⁹ Congress stated in the Robert T. Stafford Disaster Relief and Emergency Assistance Act²¹⁰ that "national defense," as used in the DPA,²¹¹ includes "emergency preparedness activities."²¹² The statutory authorization to include emergency preparedness activities in the DPA allows the President to order the prioritization of the development of any new antibiotics developed under Project BioShield.²¹³ The increasing numbers and lethality of antibiotic resistant infections combined with a lack of development in the current marketplace of new antibiotics creates a major public health threat²¹⁴ that amounts to a threat to national defense.²¹⁵

204. *Id.*

205. *Id.*

206. GOTTRON, *supra* note 174, at 7 (noting that several contracts have been cancelled, but that these contracts were not for countermeasures with the wide market base as antibiotics).

207. 50 U.S.C. app. § 2061 (1950).

208. *Id.* § 2071 (2009).

209. § 2071(a).

210. 42 U.S.C. § 5195a (2012).

211. 50 U.S.C. app. § 2152(14) (2012).

212. 15 C.F.R. § 700.1 (2014).

213. § 2071 (authorizing the prioritization of any contract to promote the national defense, which is defined to include "emergency preparedness activities"); *see also* § 5195a(b) (including, as part of the emergency preparedness activities, actions that are designed to minimize the effect of a hazard on the civilian population).

214. CTR. FOR DISEASE CONTROL & PREVENTION, *supra* note 7, at 5 (stating that antibiotic resistance is a threat because of the increasing lethality and ubiquity of antibiotic resistant infections).

215. Combating Antibiotic Resistance, Executive Order 13676, 79 Fed. Reg. 56,931 (Sept. 23, 2014) (stating that combating antibiotic resistance is a national security priority).

A major outbreak of an antibiotic resistant infection is a potential calamitous event that public health and national security officials cannot ignore. Each year, antibiotic resistant infections cause twenty-three thousand Americans to die, and cause two million to become sick.²¹⁶ A major and sudden outbreak of an antibiotic resistant infection would lead to catastrophic results.²¹⁷ Since antibiotic resistant infections are viewed as a potential public health threat,²¹⁸ the nation must prepare for the potential of such an emergency situation.²¹⁹ Therefore, the President should be able to classify the threat caused by antibiotic resistant infections as necessary for emergency preparedness,²²⁰ and should thereby order government contractors to prioritize the development of new antibiotics to combat the threat.²²¹

E. Quarantine Authority and Executive Order No. 13295

A final tool that the President could use to control the spread of antibiotic resistant infections is to utilize the federal government's authority to isolate and quarantine individuals. Executive Order No. 13295 is the authority upon which the federal government bases its ability to quarantine individuals.²²² The federal government has limited quarantine authority and does not have the broad police powers of state governments.²²³ In Executive Order No. 13295, the federal government has the authority to quarantine individuals with cholera, diphtheria, infectious tuberculosis, plague, smallpox, yellow fever, severe acute respiratory syndrome ("SARS"), and viral hemorrhagic fevers.²²⁴ Of the 17 listed antibiotic resistant infections in the CDC's report, the federal government only has

216. CTR. FOR DISEASE CONTROL & PREVENTION, *supra* note 7, at 6.

217. *See, e.g.*, Jason M. Breslow, *Illinois "Nightmare Bacteria" Outbreak Raises Alarms*, PBS (Jan. 8, 2014, 2:59 PM), <http://www.pbs.org/wgbh/pages/frontline/health-science-technology/hunting-the-nightmare-bacteria/illinois-nightmare-bacteria-outbreak-raises-alarms/> (discussing the concern over an outbreak of CRE and its potential for deadly consequences).

218. CTR. FOR DISEASE CONTROL & PREVENTION, *supra* note 7, at 5.

219. *Id.* at 6.

220. 15 C.F.R. § 700.1(c) (2006) (noting that mitigating the effects of a potential outbreak of antibiotic resistant infections through the development of new countermeasures qualifies as emergency preparedness activities).

221. *Id.* § 700.1(a) (noting that such a prioritization is within the President's discretion as long as it is needed for national defense).

222. Revised List of Quarantinable Diseases, Executive Order No. 13674, 79 Fed. Reg. 45,671 (Aug. 6, 2014).

223. *See Jacobson v. Massachusetts*, 197 U.S. 11, 26 (1905) (holding that states have a primary role in establishing public health measures, and that states have broad authority to do so based on its police powers); *see also* 42 U.S.C. § 264 (2002); *see also* 42 C.F.R. § 70.6 (2013).

224. Revised List of Quarantinable Diseases, Executive Order No. 13674, 79 Fed. Reg. 45,671 (Aug. 6, 2014).

the authority to quarantine individuals with tuberculosis.²²⁵ In order to help promote the effectiveness of antibiotics, it is crucial to slow the spread of antibiotic resistant infections.²²⁶ In preventing the spread of antibiotic resistant infections, it may be necessary at some point to quarantine people.²²⁷ The federal government's authority to quarantine individuals rests on the enumerated diseases in Executive Order No. 13295.²²⁸ Currently, the federal government does not have the authority to detain individuals with antibiotic resistant infections because antibiotic resistant infections are not listed within the Executive Order.²²⁹ The growing prevalence and lethality of various resistant infections demonstrates that the 17 listed infections in the CDC's report should be placed within the Executive Order.²³⁰ The President can add diseases to the Executive Order pursuant to the recommendations of the Secretary of HHS and the Surgeon General.²³¹ The Secretary of HHS and the Surgeon General could recommend to the President that antibiotic resistant infections be listed within the Executive Order. Taking such action does two things: (1) it provides clear authority to the federal government to quarantine infected individuals; and (2) provides a broader statement on the public health risk that such diseases pose.

In combating deadly pathogens, it is important for the federal government to have every available tool at its disposal. The need for change in regards to antibiotic resistant infections became clear in 2007 with the Andrew Speaker incident.²³² Andrew Speaker, a personal injury attorney from Atlanta, became infected with tuberculosis.²³³ The CDC believed that he was infected with extensively drug resistant tuberculosis ("XDR"), a deadly form of resistant tuberculosis.²³⁴ It turned out that Speaker was

225. *Id.*; see also CTR. FOR DISEASE CONTROL & PREVENTION, *supra* note 7, at 15–17.

226. CTR. FOR DISEASE CONTROL & PREVENTION, *supra* note 7, at 12 (discussing how the prevention of infections is an essential element of preventing the spread of antibiotic resistance).

227. See Mike Stobbe, *TB Quarantine Raises Legal Questions*, USA TODAY (June 1, 2007, 5:47 AM), http://usatoday30.usatoday.com/news/health/2007-06-01-734645277_x.htm (discussing the quarantine of Andrew Speaker, who was infected with a resistant form of tuberculosis).

228. § 70.6.

229. *Id.* (noting that Executive Order 13295 and its subsequent amendments do not include any antibiotic resistant infections other than tuberculosis).

230. See Brian Vastag & Lena H. Sun, *NIH Superbug Claims 7th Victim*, WASH. POST (Sept. 14, 2012), http://www.washingtonpost.com/national/health-science/nih-superbug-claims-7th-victim/2012/09/14/09b3742e-fe9b-11e1-b153-218509a954e1_story.html (discussing the outbreak of a superbug that killed numerous people at the NIH).

231. 42 U.S.C. § 264(b) (2012).

232. Hilary A. Fallow, *Reforming Federal Quarantine Laws in the Wake of Andrew Speaker: the "Tuberculosis Traveler,"* 25 J. CONTEMP. HEALTH L. & POL'Y 83–86 (2008).

233. *Id.* at 83.

234. *Id.* at 84–85.

infected with multi-drug resistant tuberculosis (“MDR”), which is less deadly, but it is still another virulent strain of tuberculosis.²³⁵ While health officials believed Speaker to be infected with XDR, they also chose to not exercise their quarantine authority.²³⁶ As a result, Speaker was able to board a plane and expose numerous people to MDR;²³⁷ fortunately no one became infected.²³⁸ This incident demonstrates the need for the federal government to have the clear authority to quarantine individuals with resistant infections. Quarantine is an important tool in the fight against resistant infections because it will help slow the spread of infections, and will increase the effectiveness of antibiotics already on the market.²³⁹

III. CONCLUSION

The solutions to the problem of antibiotic resistant infections proposed in this Article are drastic and less than ideal. Congressional failure to address this problem,²⁴⁰ however, suggests the need for drastic executive action. Antibiotic resistant infections have become a problem of such magnitude that it arguably represents a threat to the nation’s security. In these circumstances, the President can employ existing legislation to rapidly combat and address this problem through several means:²⁴¹ (1) through the scheduling process in the CSA, the government can better control the existing supply of antibiotics to promote antibiotic stewardship;²⁴² (2) the President can exercise his authority through the incorporation of antibiotics into Project BioShield;²⁴³ (3) the President can use the DPA to encourage the development of new antibiotics;²⁴⁴ and (4) if necessary—and appropriate based on the circumstances—antibiotic resistant infections can be incorporated into Executive Order 13295 in order to grant the federal government authority to quarantine individuals with antibiotic resistant infections.²⁴⁵ Overall, the federal government has the authority to regulate

235. *Id.* at 86.

236. *Id.* at 84; *see also* Lawrence K. Altman, *Agent at Border, Let in Man with TB*, N.Y. TIMES (June 1, 2007), <http://www.nytimes.com/2007/06/01/health/01tb.html?ref=andrewspeaker> (discussing the refusal of a border patrol agent to detain Andrew Speaker).

237. Stobbe, *supra* note 227.

238. Fallow, *supra* note 232, at 85.

239. Stobbe, *supra* note 227.

240. *Proposed Bills*, *supra* note 18.

241. Combating Antibiotic Resistance, Executive Order 13676, 79 Fed. Reg. 56,931 (Sept. 23, 2014).

242. *See* 21 U.S.C. § 841 (2012) (making it a criminal offense to unlawfully distribute controlled substances).

243. 42 U.S.C. § 247d-6a (2012).

244. 50 U.S.C. app. § 2071 (2012).

245. 42 U.S.C. § 264 (2012).

the current supply of antibiotics, develop new antibiotics, and halt the spread of antibiotic resistant infections through quarantine.²⁴⁶ Hopefully the President will not need to employ the legal options proposed in this Article. Absent action by Congress to specifically address the problem, however, the President should employ all legal solutions at his disposal to rectify this pressing and important problem.

246. *See* Combating Antibiotic Resistance, Executive Order 13676, 79 Fed. Reg. 56,931 (Sept. 23, 2014) (ordering various executive agencies to use all of the authority at their disposal to combat antibiotic resistance).