

THE EPIDEMIC OF ANTIBIOTIC RESISTANCE: A LEGAL REMEDY TO ERADICATE THE "BUGS" IN THE TREATMENT OF INFECTIOUS DISEASES

There are some remedies worse than the disease.

—Publilius Syrus¹

I. INTRODUCTION

For nearly three centuries, medieval Europe was stricken by the devastating forces of the Black Death.² The mysterious infections caused by the plague harbored the ability to destroy all living organisms in their path.³ The victims were marked by symptoms such as "gangrenous inflammation of the throat and lungs, violent pains in the chest, vomiting and spitting of blood, tumors on the groin and neck, and purple spots caused by subcutaneous hemorrhages."⁴ The epidemic killed about one-third the population of England and dramatically altered the social, political, and economical life of its survivors.⁵ The destructive power of

1. THE NEW INTERNATIONAL DICTIONARY OF QUOTATIONS 184 (2d ed. 1993).

2. See CHARLES MULLETT, *THE BUBONIC PLAGUE AND ENGLAND: AN ESSAY IN THE HISTORY OF PREVENTATIVE MEDICINE*, 1 (1956). The author notes that "no epidemic has been assessed on the same scale as the Black Death because none has had equal impact." *Id.* at 2. "The mortality of the sixteenth and seventeenth centuries owed much to the greater movement of people within the country and immigration from abroad." *Id.* The plague of course varied in type and in virulence, it did not stand alone or follow a certain pattern. *Id.* at 8. "It was often the inseparable, ferocious companion of typhus, and both were reinforced by dysentery, diptheria, cholera, smallpox, and typhoid fever." *Id.* at 8-9

3. *Id.* at 39. "In the fifteenth century, several poets saw sudden death lurking around every corner." *Id.* "This world was a thoroughfare of woe; Death spared none but summoned all; sickness was his beadle." *Id.* "Panic in England undoubtedly was, for the entire population lived in fear of the giant who spared neither proud knights, lovely ladies, sturdy peasants, nor pious priests." *Id.* at 40. "The Black Death itself everywhere produced the most diverse effects." *Id.* at 15. Its horrible mortality encouraged dissipation, persecution, and indifference. *Id.* "A hectic and hysterical disregard for moral standards, reaching to excessive sexuality and cannibalism, manifested the disintegrating blight on European civilization." *Id.*

4. *Id.* at 14. "A mild plague, characterized by swelling in the armpits or groin, some temperature with a duration of ten to twenty days, left the general health largely unimpaired and permitted the victim to go about as usual." *Id.* at 11 n. 14. "In the severe variety the early symptoms resembled those of plague: the patient became distracted, staggered about, suffered from severe headaches, thirst, and general pain." *Id.* "His eyes became red and turbid, his tongue swollen, dry, and fissured, sometimes black, sometimes white." *Id.* "Vomiting, fever, coma, and generally obstinate constipation" were other symptoms. *Id.*

5. *Id.* at 14. "The plague periodically attacked large sections of Europe for at least four hundred years, and although its mortality, extent, and influence probably never again equaled those of the mid-fourteenth century, it often reached spectacular figures and revolutionized life in limited areas." *Id.* "In popular imagination, it was a man mounted on a big black horse, or a giant striding along with his head far above the houses." *Id.* at 16. "Terrific confusion

the Black Death prompted governmental action and the development of preventative medicine.⁶

In today's society, the unprecedented rise in infectious disease mortality, elicits a red alert to our lawmakers to stem the burgeoning tide of antibiotic resistance.⁷ "Without a doubt, diseases as yet unknown, but with the potential to be the AIDS of tomorrow, lurk in the shadows."⁸ The battle is staged: Man vs. Microbe, in a quest for medical supremacy.⁹ Can we ambush the black horse of death before it is too late?

Since the discovery of penicillin in 1928, antibiotics have effectuated rapid cures for many potentially fatal diseases.¹⁰ But, the endless miracles attributed to these drugs has also led to their misuse and overuse. Due to the widespread application of antibiotics, bacteria have devised the cunning ability to out-

marked property titles, especially since the plague often carried off the last of the line." *Id.* at 24. "Lords of manors enjoyed a brief prosperity by the escheat of much property, but the immediate advent of low prices through fear of death, shortage of labor, and plentiful crops soon changed that." *Id.*

6. *Id.* at 22. "Since the problem of disease coincided with the problem of survival, the epidemic of 1349 and its recurrent manifestations drove home the necessity for governmental action." *Id.* "In the thirteenth century, public officials began to consider sanitation problems seriously." *Id.* at 30. "They commanded the cleaning of town ditches and streets and carting away of filth." *Id.* "One ordinance sought to keep swine off the streets; another expected every man to clean the street in front of his tenement; a third provided for a sweeper to keep the London streets free from litter." *Id.* Infected individuals were quarantined and houses were marked, dogs were killed, and sanctions were enforced. *Id.* at 68-70. The municipal councils established various rules governing the segregation of infected individuals and the occupancy limitations; dwellings were limited to a single family unit. *Id.* at 70.

7. See Kathy Sheridan, *The Day of the Super Bug*, WORLD PRESS REVIEW, Apr. 1991, at 40. The author notes that "fifty years ago, antibiotics were hailed as miracle drugs, 'magic bullets' in the war against once-deadly bacterial infections such as pneumonia, tuberculosis, and meningitis. For a few decades, it seemed no one would have to die of pneumonia or tuberculosis again. But then the bugs began to bite back. Using barely believable powers of mutation, they began transforming themselves into doomsday super-bugs resistant to some, or even all, types of antibiotics." *Id.*

8. *Id.* See also LAURIE GARRETT, *THE COMING PLAGUE*, 431 (1994). "We're running out of bullets for dealing with a number of these infections...patients are dying because we no longer in many cases have antibiotics that work." (quoting Joshua Lederberg, Nobel laureate).

9. See Sheridan *supra* note 7 at 40. The author comments on the problem of antibiotic resistance: "The resistant organisms that are being produced are a whole new generation of organisms... This resistance problem is one that I think is going to be a major plague for the coming century." (quoting Ralph Henderson, WHO's assistant director-general). *Id.*

10. See STUART B. LEVY, M.D., *THE ANTIBIOTIC PARADOX: HOW MIRACLE DRGS ARE DESTROYING THE MIRACLE* 6 (1992). The author notes that Alexander Fleming, coming back from a weekend vacation, went through his usual routine of looking at some of the old agar plates, and noticed the colonies of the common skin organism *Staphylococcus* had lysed seemingly by the product of a mold growing nearby. *Id.* at 34. This *Penicillium* mold produced a substance capable of bacterial cell wall lysis. *Id.* at 36. Alexander Fleming called this substance penicillin. *Id.* at 37. "Penicillin earned the accolade miracle drug because of its unique

smart the enemy.¹¹ As a result, many horrific diseases, once thought eradicated, have resurrected to impose a significant health threat.¹² The evolution of antibiotic resistance, whereby bacteria instinctively fight back, coupled with the inadequacy of new antibiotics on the test market mandates heightened concern for a plausible "superbug" epidemic.¹³

and rapid control of infectious bacteria that, before its discovery, had been fully expected to kill the patient." *Id.* at 6. "Penicillin clearly symbolized our ability to outwit and control the microbial world. *Id.* at 7. However, the drug was not man-made, but a product of molds." *Id.* "For such naturally occurring substances that killed bacteria, the term "antibiotic" was coined." *Id.* "Small amounts of penicillin cured blood-borne infections, pneumonia, and open skin wounds." *Id.* at 6. The author notes that Howard Florey is credited with producing penicillin and demonstrating the drug's success in therapy in the U.S. in the 1940's. *Id.* at 5.

11. See generally S.G. Jenkins, *Mechanisms of Bacterial Antibiotic Resistance*, NEW HORIZ, Aug. 1996. The author describes some examples of how bacteria evade antibiotics. *Id.* Specific mechanisms of resistance include reductions in cell-wall membrane permeability, alterations of antimicrobial agent target sites, enzymatic inactivation of antibiotics, and development of by-pass pathways around antimicrobial targets. *Id.* The author notes that bacteria have evolved and developed resistance to all available antibiotics to a greater or lesser degree. *Id.* See also Ron Gasbarro, *Combating Growing Bacterial Antibiotic Resistance*, AMERICAN DRUGGIST, Feb. 1996, at 49. The author comments that both France and Spain have allowed the over-the-counter (OTC) sale of penicillin, thus encouraging their unlimited and, in the absence of medical supervision, improper use. *Id.* See also LEVY, *supra* note 10, at 107. The author notes that in many parts of the world, such as Mexico, the Caribbean, South America, and Southeast Asia, antibiotics can be obtained over-the-counter in pharmacies. *Id.* OTC availability generates a laissez-faire attitude toward medicines that leads to antibiotic misuse. *Id.*

12. See Gasbarro, *supra* note 11, at 49. The author comments that human diseases thought to be under control are returning to wreak havoc. *Id.* The author mentions tuberculosis, dysentery, and malaria as examples of diseases once thought to be eradicated which have been restored. *Id.*

13. See LEVY, *supra* note 10, at 97. The author remarks that "given enough antibiotic use and its consequent selection of resistant strains, resistance increases and rears a foreboding and Hydralike head...with time, we see the creation of micro-organisms resistant, not to just one drug, but to multiple drugs." *Id.* "It is the multiply resistant bacteria appearing in different diseases and ecological settings that truly threaten our ability to treat infections successfully today." *Id.* Even amidst the optimism from the successes of penicillin, hovered words of caution. *Id.* Alexander Fleming, who discovered the drug, warned in a 1945 interview that misuse of penicillin could lead to the selection and propagation of mutant forms of bacteria resistant to the drug. *Id.* Fleming had derived such mutant bacteria in the laboratory by growing susceptible bacterial strains in increasingly higher amounts of penicillin, starting with very small amount of the drug. *Id.* The mutant bacteria altered their cells walls to be less permeable to the drug. *Id.* Fleming, hoping to avoid producing these mutants in patients during therapy, spoke out for complete courses of treatment. *Id.* Furthermore, since Fleming believed the problem would escalate when penicillin became available in oral form, he warned the medical world:

The greatest possibility of evil in self-medication is the use of too small doses so that instead of clearing up infection, the microbes are educated to resist penicillin and a host of penicillin-fast organisms is bred out which can be passed to other individuals and from them others until they reach someone who gets a septicemia or a pneumonia which penicillin cannot save.

When cough and cold season hits, antibiotics are dispensed in the millions.¹⁴ In about half of these cases, the course of therapy is considered inappropriate.¹⁵ Most patients and physicians are unaware of the harmful side effects that may result from the misuse or overuse of antibiotics.¹⁶ Furthermore, most patients envision an antibiotic as a “cure-all” and physicians, in order to maintain customer loyalty, will succumb to the patient’s demands.¹⁷ As a result, millions of people are unnecessarily exposed to a whole array of antibiotics which enhances bacteria’s ability to evade destruction.¹⁸

Despite historical predictions that infectious diseases would remain harnessed in the confines of medical technology, numerous recent events have demonstrated the reemergence of evasive “bugs”.¹⁹ With society becoming more mobile and travel abroad becoming more popular, the possibility of a Black Death

Id. The author regards these early words of Alexander Fleming as a historic prediction, the magnitude of which has yet to be seen. *Id.* See also Gasbarro, *supra* note 11. Between 1987 and 1992, the prevalence of resistance to penicillin increased more than 60 times. *Id.* Between 1989 and 1993, hospital-acquired vancomycin resistant enterococci increased about 20 fold. *Id.*

14. *Id.* The author notes that about 150 million courses of antibiotics are prescribed in the United States each year. *Id.* See also Linda F. McCaig & James M. Hughes, *Trends in Antimicrobial Drug Prescribing Among Office-Based Physicians in the United States*, 273 JAMA 214 (1995) (noting that in 1980, 1985, 1989, and 1992, antimicrobial agents were the second leading therapeutic category of drugs, behind drugs active on the central nervous system, prescribed by office based physicians in the United States).

15. See Gasbarro, *supra* note, at 49. The author notes that of the 150 million prescriptions for antibiotics each year, 50 percent of these are considered inappropriate for reasons from incorrect empirical prescribing to overenthusiastic prophylactic use. *Id.*

16. See LEVY, *supra* note 10, at 105. The author comments on antibiotics stating:

Their introduction in the 1940’s totally revolutionized the treatment of human infections, and the successes of antibiotics continue to prompt their immediate use when an infectious bacterial cause is suspected. The myth of the so-called “miracle drugs” persists today, however, as people unthinkingly demand antibiotics for ailments for which these agents have no value. In turn, their effectiveness is often diminished, tarnishing their reputations and putting us at risk from unresponding infection by drug resistant forms of bacteria.

Id.

17. *Id.* at 208. Many people envision the word antibiotic to mean a drug that will cure diseases of all kinds. *Id.* For instance, the average patient will seek an antibiotic for viral conditions such as the flu. *Id.* See also McCaig & Hughes, *supra* note 14, at 214 (noting that when a patient expected an antibiotic, more often than not, he got one).

18. See LEVY, *supra* note 10, at 215. The unnecessary and inappropriate use of antibiotics adds an economic burden to the health care system. *Id.* Given sufficient time and appropriate circumstances, there is a strong association between the magnitude of use and the emergence and spread of antimicrobial resistant strains. *Id.* at 218. The potential benefit to the patient who receives treatment with an antimicrobial drug must be weighed against the public health risk for the emergence of resistant organisms. *Id.*

19. See Robert W. Pinner et al., *Trends in Infectious Disease Mortality in the United States*, 275 JAMA 189 (1996). The authors remark that a previously unrecognized *Hantavirus* caused

landing in the United States is a risk worth considering.²⁰

Although there are several medical approaches²¹ aimed at alleviating the strain of bacterial resistance, their effects have been negligible.²² For example, the pharmaceutical industry is pursuing the development of new antibiotics to fight resistant strains, but the delayed arrival of reinforcement troops would be futile if a sudden attack would commence.²³ Therefore, in order to adequately address the resistance problem, communication among health care participants and judicious management of antibiotics should formulate the benchmark of any remedial efforts.²⁴

an outbreak of fatal respiratory illness in the American Southwest in 1993. *Id.* Contamination of a public water supply with the parasite *Cryptosporidium* was responsible for an outbreak that caused more than 400,000 cases of diarrhea and resulted in more than 4,000 hospitalizations in Milwaukee, Wisconsin. *Id.* The recent outbreak of Ebola hemorrhagic fever in Zaire, which resulted in than 296 cases, with a case-fatality rate of 79 percent, and the outbreak of plague in India in 1994 raised questions about the importation of these diseases into the United States. *Id.*

20. See Barbara E. Mintz et al., *Reported Cholera in the United States, 1992-1994: a Reflection of Global Changes in Cholera Epidemiology*, 276 *JAMA* 307 (1996). The authors note that outbreaks of cholera affecting 75 passengers on an airplane from Latin America and 5 passengers on a cruise liner from Southeast Asia accounted for 50 percent of the cases of cholera in the United States. *Id.* See also Charles Henderson, *Infectious Diseases Kill over 17 Million People a Year*, *AIDS WEEKLY PLUS*, June 3, 1996, at 22. "[W]e are standing on the brink of a global crisis in infectious diseases...no country is safe from them. No country can any longer afford to ignore their threat." *Id.* (quoting Dr. Hiroshi Makajima, WHO). In addition, the authors note that antibiotics used against many diseases are "rapidly losing their effectiveness as bacteria and other microbes develop resistance to them." *Id.*

21. See S.K. Obaro et al., *The Pneumococcal Problem*, 312 *BMJ* 1521 (1996). The authors note that *Streptococcus pneumoniae* has always been a clinically significant cause of morbidity and mortality but never more so than now because of the emergence of strains resistant to many antibiotics. *Id.* at 1527. Furthermore, one approach to this problem is to improve host protective immunity to the organism by immunization. *Id.* Although, current vaccines have a good safety record, they lack efficacy. *Id.*

22. See Leslie Alan Horvitz, *It's a War to Restore Antibiotics*, *INSIGHT ON THE NEWS*, Mar 18, 1996, at 38. The author regards the medical approaches to the resistance problem to be too little too late. *Id.* In addition, the availability and success rate of vaccinations has shown not to make a substantial difference in the mortality rate from infectious diseases. *Id.*

23. *Id.* "A once formidable arsenal of antibiotics has become the medical equivalent of blunderbusses and Gatling guns." *Id.* "During the last 12 years, the mortality rate from infectious diseases has risen 58 percent." *Id.* "Many of us feel that the way to get back at the resistance problem is to get a totally new class of antibiotics...and, in fact several pharmaceutical companies are attempting to do just that, but they have a great deal of catching up to do." *Id.* at 39 (quoting George Miller, head of preclinical infectious disease research at the Schering-Plough Research Institute in Kenilworth, N.J.). Furthermore, "there have been no new drugs for the last 2 years...all the ones that have been done in the nineties are modifications of existing drugs—so whatever resistance developed in the old ones is carrying over to the new ones...the best solution : exercise more prudence when it comes to prescribing antibiotics." *Id.* at 42 (quoting Stuart Levy, Professor at Boston's Tufts University).

24. See Robert M. Hamm et al., *Antibiotics and Respiratory Infections: Are Patients More Satisfied When Expectations Are Met?*, 43 *J. FAMILY PRACTICE* 64 (1996). "In light of the

Even though some hospitals have initiated programs aimed at curbing inappropriate antibiotic use, present day circumstances warrant a comprehensive approach to the pending epidemic.²⁵ In an era where managed care organizations are prevalent and the crux of health care takes place in the community, the opportunity exists for a legal remedy to halt the progression of a possible "superbug" tyranny.²⁶ This article sets forth the Antibiotic Resistance Epidemic in Part II.²⁷ Parts III and IV discuss the causative agents while emphasizing the need for a regulatory attack to the problem.²⁸ The remainder of this article concentrates on a proposal to extend Ohio statutory regulations to address the antibiotic resistance problem in Parts V and VI,²⁹ while dissecting the oppositions concerns about the prohibitive measure in Part VII.³⁰

II. ANTIBIOTIC RESISTANCE EPIDEMIC

Many of the killer diseases of the past such as tuberculosis, typhoid fever, diphtheria, and pneumonia have returned to wreak havoc as bacteria are increasingly resistant to antibiotics.³¹ In the last 10 years, the frequency and spectrum of

increasing cost of medical care and the growing problem of antibiotic resistance, we recommend that physicians rely more on patient interaction and less on antibiotics to achieve patient satisfaction in the care of patients with respiratory infections." *Id.*

25. See LAURIE GARRETT, *THE COMING PLAGUE*, 431 (1994). The author discusses a possible superbug epidemic. *Id.* "One of the most disturbing prospects for physicians worldwide care was the emergence around 1988 of vancomycin-resistant *Enterococcus faecium*...with Vancomycin the only remaining reliable treatment for staph and strep infections, there was great concern that resistant enterococci could share their resistant genes with the other, otherwise untreatable microbes." *Id.* See also *Overprescribing Antibiotics Creating "Superbugs"*, USA TODAY (Magazine), Oct 1996, at 4 [hereinafter "*Overprescribing Antibiotics*." "Misuse of broad-spectrum antibiotics and other practices have contributed to increasing resistance among bacteria, viruses, fungi, and parasites." *Id.* "Hospitals and physicians are trying to curb this trend through more strict prescribing of antibiotics and other measures." *Id.* Many hospitals have responded to concerns about misuse by establishing more stringent prescribing policies. *Id.* However, "control of antibiotic use in the outpatient setting is much more difficult." *Id.* at 5.

26. *Id.* "Health experts fear that the rise and spread of antibiotic resistant tuberculosis and other potentially life-threatening pathogens may push medical technology back 50 years." *Id.* "As they attempt to solve this growing problem many are supporting the implementation of preventative measures...and recommending against overprescribing antibiotics." *Id.*

27. See *infra* notes 32-46 - and accompanying text.

28. See *infra* notes 47-61 - and accompanying text.

29. See *infra* notes 67-138 - and accompanying text.

30. See *infra* notes 139-163 - and accompanying text.

31. See Simon Midgley, *Old Killers Resisting Arrest: Diseases Last Common in the 19th Century Have Returned with an Added Danger—the Prospect of an Antibiotic-resistant Super Bug*, TIMES HIGHER EDUCATION SUPPLEMENT, July 19, 1996, at 20. The author notes that many of the old diseases of the past have returned, as bacteria become increasingly resistant to antibiotics. *Id.* Leading microbiologist disease specialists are taking part in a conference to discuss how the spread of antibiotic resistance can be contained. *Id.*

antibiotic resistant infections has multiplied at an alarming rate.³² Once expected to be eliminated as a public health problem, infectious disease remains a leading cause of death and disability in the United States and worldwide.³³ Moreover, what once was thought of as primarily a hospital problem is becoming a problem in the community as well.³⁴ In today's society, with the push toward socialized medicine and the rapid growth of health care organizations, the problem of antibiotic resistance is of great concern.³⁵ In addition, various societal and technological changes that have occurred in the last decade facilitate the transmission of drug-resistant organisms.³⁶ Although not the sole factor, overuse or misuse of

32. See LAURIE GARRETT, *THE COMING PLAGUE*, 431 (1994). The author notes that "unfortunately, we played a trick on the natural world by seizing control of these [natural] chemicals, making them more perfect in a way that has changed the whole microbial constitution of the developing countries...we have changed the whole face of the earth by using antibiotics." *Id.* See also *Overprescribing Antibiotics*, *supra* note 25, at 1. "Antibiotic-resistant pathogens are emerging at an alarming rate and treatment options are shrinking," warns Terrance O. Kurtz, chief epidemiologist at Des Moines General Hospital and associate professor of internal medicine at the University of Osteopathic Medicine. *Id.* The resistance problem is nothing new, "but it is more of a concern now than in the previous two decades because it is occurring so rapidly." *Id.* "How should physicians handle the problem of drug resistance?" *Id.* The article notes that physicians must "slow the spread of resistance to antibiotics, especially considering the speed with which common pathogens are adapting." *Id.* "The incidence of penicillin resistance to *Streptococcus pneumoniae* is now 25-35%, just a few years ago, there was no resistance at all." *Id.* (quoting Anthony Silvagni, Dean of the University of Health Sciences College of Osteopathic Medicine).

33. See HORVITZ, *supra* note 22. The author notes that the threat is hardly limited to this country, according to a statement issued at the end of 1994 by the World Health Organization (WHO), antibiotic resistance has reached epidemic proportion in many parts of the globe. *Id.* The consequences for impoverished nations, with few medical resources and high rates of infectious diseases are incalculable. *Id.* "We do know that people are dying because of resistant infections that once could be treated." *Id.* (quoting Stuart Levy, author of the antibiotic paradox).

34. See Steven P. Gelone, Pharm D., *Bacterial Resistance: Preparing for the Post-Antimicrobial Era*, *PHARMACY TIMES*, May 1995, at 31. The author regards the emergence of resistance in the community environment as occurring mainly because of the selective pressure of antimicrobial use. *Id.* at 32. Additionally, as the proportion of families with two working parents increases, the need for enhanced infection control practices in the day care environment to decrease the spread of infectious diseases among children may be needed. *Id.* at 38.

35. *Id.* "[T]he idea of multiply resistant bacterial infection is no longer a threat; it is a reality of patient care..." *Id.*

36. See LAURIE GARRETT, *THE COMING PLAGUE*, 431 (1994). The author comments on the improper use of antibiotics as "experiments going on all the time in people, creating genuinely pathogenically new organisms." *Id.* See also *Overprescribing Antibiotics*, *supra* note 25, at 5. The author states that "epidemiologists have discovered that growing resistance to potentially life-saving drugs can be attributed to misuse of broad-spectrum antibiotics; increasing use of prosthetics and invasive diagnostic and therapeutic procedures; growing consumer demand for antibiotics;...routine use of penicillin in cattle and chicken feed; and lax rules governing the use of antibiotics in other countries." *Id.* at 2-3. Also, with society becoming more mobile, increasing international travel, and more children attending day care centers, the problem seems to be at an apex. *Id.*

antibiotics plays a major part in the emergence of the pending epidemic.³⁷

Although antibiotics are deemed harmless, they harness the ability to alter the future of our nation's health.³⁸ The role of an antibiotic is to gain access within a bacterial cell.³⁹ Once inside, the agent corrupts the processes which keep bacteria alive.⁴⁰ There exist several classes of antibiotics which have unique focal points of attack against bacteria.⁴¹ In general, antibiotics enter our bloodstream to seek out and destroy bacterial cells. However, the stubborn bacteria have devised mechanisms of resistance to evade the persistent antibiotics.⁴² Once a bacterial cell mutates to avoid destruction, this mode of resistance is passed on to their progeny.⁴³ As a result, narrow spectrum antibiotics, which have a limited use to

37. See Gasbarro *supra* note 11, at 54. Bacteria are becoming increasingly resistant to the antibiotics used against them which is caused through antibiotic misuse and overuse. *Id.* Bacterial strains that are resistant to standard drugs have developed as a result of the continued misuse of medicines, particularly antibiotics. *Id.* Antibiotic resistance has spread to a number of infectious diseases, making it an international concern. *Id.* See also *Overprescribing Antibiotics*, *supra* note 25, at 4. The author notes that the misuse of broad-spectrum antibiotics and other practices have contributed to increasing resistance among bacteria. *Id.*

38. *Id.*

39. See Gasbarro, *supra* note 11, at 49.

40. *Id.* For example, cell-wall synthesis is disrupted by vancomycin, the penicillins, the cephalosporins, the mono-bactams, bacitracin, and carbapenems. *Id.* The metabolism of folic acid that provides bacteria with energy is disrupted by dapsone, isoniazid, trimethoprim, and the sulfonamides. *Id.* at 50. Fluoroquinolones interfere with microbial DNA replication and protein synthesis is inhibited by the macrolides, tetracycline, the aminoglycosides and mupirocin. *Id.*

41. See Michelle Meyer, *Antibiotics: Are They the Newest Abused Drug*, BETTER HOMES AND GARDENS, Nov. 1996, at 72. The author lists some classes of antibiotics and the types of infections they are used to treat. *Id.* Antibiotic common uses: Ampicillin or Amoxicillin—middle-ear and urinary tract infections, Bactrim—urinary tract infections, Aids-related infections, diarrheal infections, Biaxin—bronchitis, Legionnaires disease, and sexually transmitted diseases, Ceclor—a general antibiotic used for skin, middle-ear, and upper respiratory infections, Cipro—urinary tract, bone and joint infections, and traveler's diarrhea due to bacteria, Keflex—skin, soft-tissue and respiratory infections, Penicillin—strep throats, rheumatic fever, gonorrhea, and syphilis. *Id.* (relying on information by Mathew L. Lenz, M.D., Houston internist).

42. See Gelone, *supra* note 34, at 32-39. In general, the author describes the development of bacterial resistance via four mechanisms: enzymatic destruction or inactivation of the antimicrobial agent or its metabolite(s), alteration of the target site, decreased drug entry to the receptor site, and synthesis of an altered metabolic pathway. *Id.*

43. See Levy, *supra* note 10 at 103. The author comments on bacterial resistance in stating:

Bacterial resistance to antibiotics is not a new creation of the past 40 years. It has, however, become a new clinical problem, because preexistent, naturally occurring plasmids have become equipped with previously rare resistance genes. The combination of resistance genes on transferable plasmids has enhanced spread of resistance. Bacteria have demonstrated to us a remarkable fluidity in their genetic material. Under the threat of antibiotics, a small number of them can achieve a

begin with, are rendered less effective.⁴⁴ Therefore, physicians resort to prescribing the newer, broad spectrum agents to avoid potential resistance.⁴⁵ With the over-prescribing of the broad spectrum agents, resistance is soon to follow and maintaining control of infectious diseases may fall outside the grasp of existing antibiotics.⁴⁶

III. WHERE ARE THE "BUGS" IN OUR HEALTH CARE SYSTEM?

In recent years, the inadequate management of infectious diseases has been a major factor in the dramatic rise of health care costs.⁴⁷ The basic framework of our health care system includes patients, providers, and payers. The existing problem of antibiotic resistance is aggravated by all three entities.⁴⁸ First, a major problem exists due to patient inconsistencies in seeking treatment and fol-

tenacious survival mode, either by chromosomal mutation, or more frequently, by acquisition of new genes. These events allow them to persist and grow in the direct path of what had been efficient killing agents, the antibiotics.

Id.

44. *Id.* Narrow spectrum agents are limited to specific types of bacteria and have a limited use, whereas broad spectrum agents kill a wide variety of organisms and are often used by physicians when the bacteria is unknown. *Id.* at 44. Penicillin is an example of a narrow spectrum antibiotic to which bacteria have developed significant resistance over the years. *Id.* Cephalosporins, adaptations of the penicillin structure, are broad spectrum agents useful against a variety of bacteria. *Id.*

45. See Anne Novitt-Moreno, *Antibiotics: What's Happening to our Miracle Drugs?*, CURRENT HEALTH, Dec. 1995, at 6. The author states that when physicians are faced with a resistance problem, they can add a second antibiotic that attacks the bacteria in a different way or they can switch to an entirely different antibiotic. *Id.* at 7.

46. *Id.* The author notes that the problem with adding or switching antibiotics is that it gives bacteria a look at more of our weapons and every time bacteria are exposed to a new antibiotic, there's always a chance those that are not killed will develop a new kind of resistance. *Id.* See also Mark Nichols, *Outbreak: Doctors Are Struggling to Control Drug Resistant Bacteria*, MACLEAN'S, Sept. 9, 1996, at 42. The author notes that "Doctors dread the day when events in the microbial world could create a kind of superbug." *Id.* "Bacteria are sexually promiscuous, reproduce rapidly and they can swap genes with ease." *Id.*

47. See McCaig & Hughes, *supra* note 14 at 217. The study resulted in a finding that the use of cephalosporins had been increasing. *Id.* The rationale for the increased use of the new drugs has been questioned, since they appear to be no more effective for many diseases than the older agents and are more expensive. *Id.* These changing patterns have implications for patients, especially children. *Id.* Such trends can increase health care costs and lead to the development of antimicrobial resistance. *Id.*

48. *Id.* See also Richard Cash, *Inappropriate Treatment for Dysentery: Perverse Incentives and Inadequate Information May Accelerate Antibiotic Resistance*, 313 BMJ 181 (1996). The author states:

If interventions are to modify inappropriate prescribing they "must touch all groups in the medication cycle (consumer, service provider, supplier, and manufacturer), in order to reinforce behaviour change." A better informed consumer is an

lowing through with the prescribed therapy.⁴⁹ For example, some individuals will visit the doctor for any sneeze, snuffle, or cough, while others who need medical attention oftentimes do not receive it.⁵⁰ Likewise, those patients who reap only a psychological benefit from a visit to a doctor, will leave with an unnecessary prescription.⁵¹ In addition, lack of patient compliance poses a serious threat.⁵² Patients contribute to the problem by discontinuing therapy prematurely, not tak-

important element in reducing the use of inappropriate drugs. Practitioners and drug sellers focus on the individual, not the group. The opinion and behaviour of the consumer is important in both compliance with treatment and selection of the most appropriate drug. At a minimum, the public should know what constitutes the best treatment and that more expensive drugs are not necessarily more effective. Treatment programmes should be demystified, and the public should be informed of the benefits and risks of different forms of treatment. Though we are beginning to understand how economics and practice based incentives influence prescribing practices, we are quite ignorant about how beliefs affect patient compliance. An interdisciplinary approach involving physicians, economists, behavioural scientists, communication specialists, manufacturers, and others will need to address the problem of inappropriate use of antibiotics if we are to avoid the increasingly alarming reports of worldwide resistance.

Id. at 183.

49. See *Overprescribing Antibiotics*, *supra* note 25, at 4. The article comments on patient behavior in taking antibiotics. *Id.* “[P]atients who currently view antibiotics as ‘cure-alls’ must learn that aches and sniffles associated with common colds and flu do not respond to antibiotic therapy. In addition to demanding drugs, patients are contributing to antibiotic resistance through noncompliance...more than half of American adults who receive antibiotics fail to take all of the prescribed doses of the drug.” *Id.*

50. See *generally*, Gasbarro, *supra* note 11. The author remarks on patient compliance as being a factor which contributes to the advent of antibiotic resistance. *Id.*

51. See Hamm et al., *supra* note 24 at 56. The results of the study: Sixty-five percent of the 113 patients with respiratory infection expected antibiotics. *Id.* Physicians had some ability to perceive this expectation and frequently prescribed antibiotics for patients who expected them. *Id.* Antibiotics were prescribed to over 75% of patients with sinusitis or bronchitis and to 18% of those diagnosed with only viral infections. *Id.* See also Arch G. Mainous et al, *Antibiotics and Upper Respiratory Infection: Do Some Folks Think There is a Cure for the Common Cold?*, JOURNAL OF FAMILY PRACTICE, April 1, 1996, at 359. Even though there is no cure for the common cold, physicians may still prescribe antimicrobial agents, believing that patients expect to receive them. *Id.* Although evidence suggests that many patients do not enter the therapeutic encounter expecting a prescription for antibiotics, physicians may interpret patient behaviors as indicating a desire for antibiotics. *Id.*

52. See LEVY, *supra* note 10, at 220. The author states:

An individual should know when, why, and for how long the prescribed antibiotic should be taken. He or she should ask these questions of the physician and then follow the directions for use. If the antibiotic is given to treat a bacterial infection, it needs to be taken for the entire course of therapy and not simply until the symptoms disappear. Resistant forms of the causative bacteria can emerge and increase in number if the drug is stopped before a treatment course is completed. Once these resistant forms are numerous, subsequent treatment with that antibiotic fails.

Id.

ing the correct dose, or using leftover medicine from a family member or friend.⁵³

Due to physician's virtually unrestricted prescribing ability, they represent the most significant force behind the emergence of antibiotic resistance.⁵⁴ Often, physicians rely on information supplied by sales representatives of drug companies when prescribing antibiotics.⁵⁵ As a result, the broad spectrum, more expensive antibiotics are overprescribed.⁵⁶ Other physician contributions to the problem include choosing an ineffective antibiotic, incorrect doses, the inappropriate use in uncomplicated viral diseases, and reliance on antibiotic therapy that leads to the exclusion of surgical intervention.⁵⁷ Moreover, many physicians, in an effort to maximize their customer base, will succumb to the antibiotic seeking patient's demands.⁵⁸ This result occurs notwithstanding a corresponding diagnosis which recommends alternative therapy.⁵⁹

The payers in our health care system possess the power of the purse, but have forgone any affirmative action to diminish the unrestrained bugs from infecting society. Although insurance companies have made significant progress in decreasing health care costs, little has been done in an area of utmost concern—

53. *Id.* at 209. "If antibiotics are "prescribed-only" drugs, how do individuals gain access to them? There are many ways, not the least of which is storing and using leftover drugs." *Id.* When the author asked people what they do with medicines they do not take, the vast majority respond that they keep them for later use. *Id.* "In any number of homes, should you open the mirrored bathroom cabinets, you'll find bottles of unused drug tablets and liquids." *Id.*

54. See Gasbarro, *supra* note 11, at 49. The author remarks on the role the physicians plays in contributing to the problem of antibiotic resistance. *Id.*

55. See Cash, *supra* note 48 at 181. The most up to date information available to health care providers comes from drug company representatives, whose main aim is to sell their products. *Id.* Textbooks are uncommon and usually outdated, and peer reviewed journals are rarely available. *Id.* Obtaining correct information is not easy. *Id.* Practitioners who are trying to increase their income may resort to polypharmacy or prescribe drugs that maximize profits. *Id.*

56. See LAURIE GARRETT, *THE COMING PLAGUE*, 431 (1994). The author comments on the improper use of antibiotics. *Id.* "It's hard to put the large view into day-to-day medicine...you can't sue a doctor for violating an ecosphere, but you can sue a doctor for failure to give an antibiotic that you think may have enhanced the possibility of patient survival." *Id.* (quoting Mark Lappe, author of *Germes That Won't Die*). See also *Overprescribing Antibiotics*, *supra* note 25, at 5. "Many physicians who have been in practice a long time have bad habits...We all get used to using certain antibiotics...If an antibiotic does the job for us, we use it, even if a more specific antibiotic is available." *Id.* (quoting Terrance O. Kurtz, Chief Epidemiologist at Des Moines General Hospital).

57. See Gasbarro, *supra* note 11 at 51 (Table 1). Table 1 lists the ways in which a physician or patient may contribute to bacteria's ability to develop resistance. *Id.*

58. See Cash, *supra* note , at 181. The author notes that physicians have suggested that they are only trying to maintain their customer base by responding to customer demands when they overprescribe or use the latest, most expensive drugs. *Id.*

59. See Hamm et al., *supra* note 24, at 56. The author says that a physician may feel a duty to treat the patient presenting with a mild but uncomfortable illness with antibiotics, even if the likelihood of improving the outcome is small. *Id.*

antibiotic resistance.⁶⁰ Due to the inadequate control of the pending epidemic by medical remedies, the remainder of this article focuses on why legal regulations are needed to hinder the advancing army of resistant bacteria.⁶¹

IV. WHY WE NEED TO REGULATE ANTIBIOTIC PRESCRIPTIONS

Recent studies indicate that the infectious disease mortality rate has risen nearly sixty percent, becoming the third leading killer of Americans.⁶² Furthermore, the Center for Disease Control (CDC) estimates that more than half of the infection related deaths involve resistant bacteria.⁶³ Although physicians

60. See LEVY, *supra* note 10, at 238. The author comments on the cost to society and the individual of antibiotic resistance, by stating :

Certainly the most critical consequence of antibiotic resistance is the compromised therapy of human disease. Another mounting and disturbing consequence of resistance, however, revolves around the price tag for treatment. Someone must pay for the higher costs of newer drugs that are needed to combat resistant bacteria. Medical insurance companies, the government, and the individual now face, and will continue to face, higher and higher prices for the new antibiotics being developed to treat the multiresistant forms of bacterial disease.

Id.

61. See Mainous et al., *supra* note 51, at 359. The seemingly benign act of prescribing an antibiotic such as amoxicillin for a cold does little or no physical harm to the patient and keeps the practice economically viable. *Id.* This particular perspective may be based on practice management behaviors deemed effective in a fee-for-service model of health care delivery. *Id.* In closed-panel managed care organizations, the ability of the patient to change physicians may be greatly impeded, thereby decreasing the perceived economic threat of patients leaving the practice if they do not receive antibiotics for colds. *Id.* The author also adds:

Even guidelines to be voluntarily followed have shown positive effects in increasing the appropriate use of antibiotics. Although most of the guidelines have been proposed for small closed systems such as hospitals, they may be useful to managed care organizations. However, open systems, such as the general community of physicians, could also be influenced by a clinical guideline for treating the common cold. Evidence suggests that clinical guidelines for medical practice can be particularly effective when presented in the context of a specific educational intervention but seldom change practice when disseminated through publication in journals or unsolicited mailed material.

Id.

62. See Pinner et al., *supra* note 19, at 189. The authors conclude that between 1980 and 1992, the death rate due to infectious diseases as the underlying cause increased 58 percent. *Id.* "Despite historical predictions that infectious diseases would wane in the U.S., recent data suggests that infectious disease mortality rate has been increasing steadily." *Id.*

63. See Horvitz, *supra* note 22, at 38. "Exact statistics are hard to come by...what we don't know is whether they died of a heart attack and also had an infection or died of the infection itself...we do know that people are dying because of resistant infections that once could be treated." *Id.* (quoting Stuart Levy, author of THE ANTIBIOTIC PARADOX).

and patients cannot be deemed fully responsible, the misuse and overuse of antibiotics poses a significant threat to the existing arsenal of antimicrobials.⁶⁴

Since major drug manufacturers have abandoned the replenishment of the antibiotic arsenal until recently, the hypothetical epidemic becomes a reality with no assistance from reinforcement troops.⁶⁵ For example, no new antibiotics have been developed for the last two years.⁶⁶ Since it takes fourteen years of research and approximately 400 million dollars for a drug to reach the market, the resistance problem appears to be far from under control.⁶⁷ Therefore, in order to remain one step ahead of the bacteria, the only plausible remedy is to construct and enforce legal regulations.⁶⁸

In the 1970's, regulatory agencies played a major part in preserving the health and safety of our nation.⁶⁹ Once again, as the health of our nation is put in jeopardy, it is time to bring forth our public representatives to devise a regulatory remedy. A physician can be likened to a nuclear power plant to allow regulato-

64. See *Overprescribing Antibiotics*, *supra* note 25, at 4. The article notes that growing resistance to potentially life-saving drugs can be attributed to misuse of broad-spectrum antibiotics. *Id.* Although, health experts agree that any use of antibiotics can potentially lead to resistance, the misuse and overuse of antibiotics has contributed greatly to the growing problem. *Id.*

65. See Horvitz, *supra* note 22, at 38. "Many drug manufacturers have abandoned the development of antibiotics almost entirely . . . the reason, not surprisingly, is economics . . . drug companies have concentrated on cardiovascular and abandoned infectious diseases . . . Patients given cardiovascular medication such as beta blockers will take the medicine for the rest of their lives while people with infections will only need a drug for the duration of their illness, usually no longer than a week or two." *Id.* (quoting Stuart Levy, author of *THE ANTIBIOTIC PARADOX*).

66. *Id.* Levy underscores a more important problem: "There have been no new drugs for the last 2 years . . . all the ones that have been done in the nineties are modifications of existing drugs—so whatever resistance developed in the old ones is carrying over to the new ones." *Id.*

67. See Novitt-Moreno, *supra* note 45, at 6. The author asks: "How do we stop the superbugs?" *Id.* "Do we just keep on inventing new antibiotic weapons?" *Id.* "We could, but there's a catch: It takes about 14 years of research and almost 400 million dollars to develop every new antibiotic . . . And after all that work and money, some dangerous bacteria could find a way to resist it almost overnight. . . . Scientists believe that instead of making new antibiotic weapons, we should be more careful using the ones we already have." *Id.*

68. See Gasbarro, *supra* note 11, at 49. The author concludes that antibiotics are still extremely effective managers of bacterial infection, and the risks posed by resistance can be greatly diminished through use of judicious medication use. *Id.*

69. See ROGER W. FINDLEY & DANIEL A. FARBER, *Environmental Law in a Nutshell*, 23 (3d ed. 1992). The authors comment on the importance of NEPA in stating: "prior to the passage of NEPA, some agencies contended they lacked the statutory authority to consider environmental issues . . . For example, the Nuclear Regulatory Council (NRC) contended that the thermal pollution caused by nuclear power plants was beyond their jurisdiction . . . One important result of NEPA is to ensure every agency has the authority to consider the environmental consequences of its actions." *Id.*

ry action to prevent a potential disaster.⁷⁰ This analogy is not farfetched. In each case, the physician and power plant are granted a license which allocates permission to the holder to conduct activities within the confines of the license.⁷¹ However, if the privilege is abused to the point of jeopardizing the health and safety of society, the license can be revoked or suspended.⁷² Just as the nuclear power plant is subject to health and safety guidelines, a physician should meet guidelines when prescribing antibiotics. Although physicians are subject to tort liability restraints,⁷³ they possess "the power of the pen" and are virtually unrestricted when it comes to prescribing antibiotics.⁷⁴ The physician has been confined in other areas of medicine with prescribing limitations.⁷⁵ These limitations

70. See *Northern States Power Co. v. Minnesota*, 447 F.2d 1143 (8th Cir. 1971), aff'd 405 U.S. 1035 (1972). The court concluded :

Thus, through direction of the licensing scheme for nuclear reactors, Congress vested the AEC with the authority to resolve the proper balance between desired industrial progress and adequate health and safety standards. Only through the application and enforcement of uniform standards promulgated by a national agency will these dual objectives be assured.

Id.

71. See Atomic Energy Act of 1954, 42 U.S.C.A. § 2011-2282. See also FINDLEY & FARBER, *supra* note 69 at 191. The authors note that the primary purpose of regulation is to protect human life and the environment from excessive exposure to radiation. *Id.* The Nuclear Regulatory Commission (NRC) exercises broad regulatory and licensing authority over essentially all activities related to civilian nuclear materials. *Id.*

72. See *Pacific Gas & Electric Co. v. State Energy Resources Conservation & Development Comm'n*, 461 U.S. 190 (1983) (holding that the construction of nuclear power plants was conditioned on a determination by a state agency that adequate storage facilities and means of disposal were available for nuclear waste and approved by NRC).

73. Examples of tort liability include, but are not limited to, medical malpractice claims where the practitioner has not met the standard of care in the treatment of a certain disease state or condition.

74. There are currently no limitations placed on the ability of a physician to prescribe antibiotics. See generally OHIO REVISED CODE. been confined in other areas of medicine with prescribing limitations.⁷⁵

75. Among the various restrictions imposed on practitioners are the following:

21 C.F.R. § 1306.04 (1996) which states:

(a) A prescription for a controlled substance to be effective must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice.

OHIO REV CODE ANN. § 4731-11-05 which states:

(A) A physician shall not utilize anabolic steroids, growth hormones, testosterone or its analogs, human chorionic gonadotropin (HCG), or other hormones for the purpose of enhancing athletic ability.

(B) A physician shall complete and maintain patient medical records which

mainly encompass areas which may present a danger to society if permitted to run

accurately reflect the utilization of any substance or drug described in this rule. Patient medical records shall indicate the diagnosis and purpose for which the substance or drug is utilized, and any additional information upon which the diagnosis is based.

(C) A violation of any provision of this rule, as determined by the board, shall constitute failure to use reasonable care discrimination in the administration of drugs, as that clause is used in division (B) (2) of section 4731.22 of the Revised Code; and "a departure from, or failure to conform to, minimal standards of care of similar practitioners under the same or similar circumstances, whether or not actual injury to the patient is established," as that clause is used in division (B) (6) of section 4731.22 of the Revised Code.

OHIO REV CODE ANN. § 4731-11-04 (Banks-Baldwin 1996) which states:

(A) A physician shall not utilize a schedule III or IV controlled substance for purpose of weight reduction unless it has an FDA approved indication for this purpose and then only in accordance with all of the provisions of this rule.

(B) A physician may utilize a schedule III or IV controlled substance for the purposes of weight reduction in the treatment of obesity only as an adjunct, in accordance with the FDA approved labeling for the product, in a regimen of weight reduction based on caloric restriction, provided that all of the following conditions are met:

(1) Before initiating treatment utilizing a schedule III or IV controlled substance, the physician determines through review of his own records of prior treatment, or through review of the records of prior treatment which another treating physician or weight-loss program has provided to the physician, that the patient has made a substantial good-faith effort to lose weight in a treatment program utilizing a regimen of weight reduction based on caloric restriction, nutritional counseling, behavior modification, and exercise, without the utilization of controlled substances, and that said treatment has been ineffective...

(2) The physician shall not initiate or shall discontinue utilizing all schedule III or IV controlled substances immediately upon ascertaining or having reason to believe:

(a) That the patient has failed to lose weight while under treatment with a controlled substance or controlled substances over a period of fourteen days, which determination shall be made by weighing the patient at least every fourteenth day, except that a patient who has never before received treatment for obesity utilizing any controlled substance who fails to lose weight during his first such treatment attempt may be treated with a different controlled substance for an additional 14 days...

(C) A violation of any provision of this rule, as determined by the board, shall constitute failure to use reasonable care discrimination in the administration of drugs, as that clause is used in division (B) (2) of section 4731.22 of the Revised Code; and "a departure from, or failure to conform to, minimal standards of care of similar practitioners under the same or similar circumstances, whether or not actual injury to the patient is established," as that clause is used in division (B) (6) of section 4731.22 of the Revised Code.

afoul of certain therapeutic recommendations.⁷⁶ A physician who violates the prescribing restrictions may have their license suspended or revoked.⁷⁷

Some physicians and other experts in the medical field agree that guidelines and regulations need to be imposed on antibiotic prescribing before the resistance problem becomes uncontrollable.⁷⁸ One way that doctors can aid the battle

76. *See generally*, OHIO REV CODE ANN. Drug Laws of Ohio (Banks-Baldwin 1996). The restrictions which exist on a physicians prescribing ability deal with controlled substances, drugs entities having a high potential for abuse whether it is physical, psychological or both. *Id.* This is done to ensure the health and safety of individuals in the administration of health care. In the antibiotic arena, patients and physicians have become addicted to the healing power, envisioning antibiotics as "cure-alls." Therefore, due to the psychological abuse potential of antibiotics, they should be dealt with in a similar manner to controlled substances.

77. *See* OHIO REV CODE ANN. § 4731.22 (Banks-Baldwin 1996) which states in part that:

The state medical board, pursuant to an adjudicatory hearing under Chapter 119 of the Revised Code and by vote of not fewer than six of its members, shall, to the extent permitted by law, limit, revoke, or suspend a certificate, refuse to register or refuse to reinstate an applicant, or reprimand or place on probation the holder of a certificate for.... Failure to use reasonable care discrimination in the administration of drugs, or failure to employ acceptable scientific methods in the selection of drugs or other modalities for the treatment of disease.

OHIO REV CODE ANN. § 4731.22 (A) (2) (Banks-Baldwin 1996). License suspensions and revocations are well documented under Ohio case law. *See, e.g.,* Gingo v. State Medical Board, 564 N.E.2d 1096 (Ohio App. 1989). The court held that "Dr. Gingo's weight loss 'system' is precisely the opposite of what one would expect to find in a program purported to enhance overall good health. In truth, his proposed solution to an admittedly significant problem—obesity—ultimately promotes a far more alarming epidemic: drug misuse...." *Id.* at 1099; Arlen v. State, 399 N.E.2d 1251 (Ohio 1980) (stating that "the purpose of the General Assembly in providing for administrative hearings in particular fields was to facilitate such matters by placing the decision ... with boards... equipped with the necessary knowledge and experience pertaining to a particular field.") (quoting Farrand v. State Medical Board, 151 Ohio St. 222, 224 (1949)) *Id.* at 1254. In *Arlen*, the court held that the physician's licens should be suspended for improperly dispensing drugs. *Id.*; Sickling v. State Medical Bd., 575 N.E.2d 881, 883 (Ohio App. 1991) (holding that physician's license be revoked for violating R.C. 4731.22 (B), which states in part: "Failure to use reasonable care discrimination in the administration of drugs, or failure to employ acceptable scientific methods in the selection of drugs...in the treatment of disease..."); Stegall v. Ohio State Medical Bd., 635 N.E.2d 1291 (Ohio App. 1993) (holding that the board's adoption of weight control rule was properly based on medical testimony and board's own expertise) The court added "there can be no question that the board has the ability to adopt rules setting specific minimum standards of care by adopting administrative regulations." *Id.* at 1294; Roy v. Ohio State Med. Bd., 655 N.E.2d 771 (Ohio App. 1995) (affirming the authority of State Medical Board to revoke physician's license to practice includes the authority to revoke it permanently); *But see* In re Williams, 573 N.E.2d 638 (Ohio 1991) (affirming Court of Appeals reversal of determination by State Medical Board that physician had failed to conform to minimal standards of medical practice by prescribing controlled substances as part of a weight control treatment regimen).

78. *See Overprescribing Antibiotics, supra* note 25, at 4. The article notes that many hospitals have responded to concerns about misuse by establishing more stringent prescribing

against bacteria is to utilize judicious management in prescribing drugs.⁷⁹ However, when the physician in a community setting depends on a strong customer base for their livelihood, the physician seems left without an alternative when confronted with an antibiotic seeking patient.⁸⁰ A regulatory scheme will promote uniformity and enable physicians to "just say no."⁸¹ Another advantage to a regulatory program is the prevention of doctor shopping.⁸² If a patient leaves a doctor's office empty-handed, they will be less likely to seek another provider if they will be met with similar results.⁸³ The regulations would also serve as an educational tool to enlighten physician and patient understanding of the extent of a potential disaster.⁸⁴ As a result, when faced with legal regulations, physicians will be less likely to prescribe sight unseen or cause unknown.⁸⁵ Furthermore, patients will be less likely to expect antibiotics and will be unable to "go around the corner" to receive them.

policies. *Id.* In some institutions, broad-spectrum antibiotics can be prescribed only by infectious disease specialists. *Id.* "By restricting the use of some antibiotics, we can stem the tide of resistance until new antibiotics hit the market." *Id.* (quoting Anthony F. Ognjan, Chief of Infectious Diseases, Mount Clemens (Mich.) General Hospital).

79. See Cash, *supra* note 48 at 181. The author states that physicians have suggested that they are only trying to maintain patient satisfaction by responding to customer demands when they overprescribe or use the latest, most expensive drugs. *Id.*

80. *Id.* Practitioners who are trying to maximize profits may resort to polypharmacy or prescribe drugs that increase their income. *Id.* The author asks: "What can be done about this behavior?" *Id.* The author responds: "Educational programs are necessary, but how the information is presented and reinforced is critical." *Id.* In an attempt to change prescribing patterns for treating diarrhea in a government hospital in Mexico, two techniques were used: (1) they involved the physicians in developing a treatment algorithm and, (2) they performed and publicized periodic audits of each physician. *Id.* The use of antibiotics dropped from 80% to 30% of all cases of diarrhea seen in the clinic. *Id.* Moreover, these changes were sustained 18 months after starting the program. *Id.*

81. See Horvitz, *supra* note 22, at 39. "A lot of people say, 'if my physician doesn't give a drug to me, I'll get it from somewhere else.'" *Id.* (quoting Amy Magen, a spokeswoman for Eli Lilly Drug Company). The author adds: "This is one time when just saying no to drugs may accomplish its objective." *Id.*

82. The regulatory proposal is set forth in Section IV(B), *infra*. See also LEVY, *supra* note 10 at 212. The author states: "We are at a point in medical history where people expect a pill for every ill." *Id.* "Whom do we blame, the physician or the patient, when an antibiotic is obtained for the common cold?" *Id.* The author notes: "People welcome the report from the local mechanic that all their car needed was an adjustment, a new spark plug, but not a total motor overhaul...we do not argue about paying for his time and expense.... Why then should patients be disappointed when the doctor says that their viral disease needs only aspirin, fluids, and rest?" *Id.* at 213.

83. *Id.* at 221.

84. *Id.* The author notes that "by using these drugs effectively, each one of us protects the world population from the continued emergence and spread of resistance determinants...we must take responsibility for using antibiotics properly, since this will protect the future health of ourselves, our families, and our whole society." *Id.* at 221.

85. See *supra* notes 79-84 and accompanying text.

Legal restrictions on antibiotic use will also provide third party payers with the necessary ammunition to mount an attack of their own. The majority of prescriptions in the U.S. are paid by third party prescription insurance plans.⁸⁶ The regulations will enable the insurance company to allow monetary incentives for those patients and physicians complying with the regulations.⁸⁷ Most prescription payers already have the necessary equipment to enforce an additional restriction.⁸⁸ The insurance companies have a drug utilization review (DUR) program which recognizes and corrects other therapeutic inadequacies.⁸⁹ The DUR program has been successful at enhancing therapeutic outcomes and diminishing

86. See LEVY, *supra* note 10 at 221. The majority of Americans are able to have reduced costs of prescriptions through some type of prescription insurance plan. *Id.* "Someone must pay for the higher costs of newer drugs that are needed to combat resistant bacteria." *Id.* at 238. "Medical insurance companies, the government, and the individual now face higher and higher prices for the new antibiotics being developed to treat the multiresistant forms of bacterial disease." *Id.* See also Cash, *supra* note 48. Inappropriate drugs cost more because adequate treatment can be achieved with fewer and less expensive drugs. *Id.* at 181. Also, in describing methods incorporated in a managed care setting, the author notes that such methods might be effective for physicians working as employees in hospitals or health maintenance organizations, where standards of case management can be maintained. *Id.*

87. *Id.* "If interventions are to modify inappropriate prescribing they must touch all the groups in the medication cycle." *Id.* The author notes that a better informed consumer is an important element in reducing the inappropriate use of antibiotics. *Id.* See also KLAIS HEALTH NETWORK PROVIDER DIRECTORY, Akron, Ohio (1997). The directory notes that "your decision whether or not to use a Klais Health Network provider may affect the level of the benefits you receive...you are free to choose a provider which is not part of the Klais Health Network, but you will generally receive lower out of pocket charges when utilizing a Klais Health Network provider...because our providers have agreed to supply health care services at pre-negotiated discounts." *Id.*

88. Telephone Interview with Michael Dennis, Registered Pharmacist in Canton, Ohio (Jan. 15, 1997). In addressing the third parties relationship to prescription filling, Mr. Dennis states:

The third party insurance companies have a great deal to do with drug therapy. I am constantly calling them for an override code or approval for one thing or another. For example, if a patient is attempting to get an early refill on a medication, the insurance company will want to know the reason before payment is granted. I will phone the doctor to check the dosing on the medication and relay this information to the insurance carrier to get an override.

Id.

89. *Id.* Mr. Dennis further remarks on the successes of the DUR program:

The DUR program combines a vast array of therapeutic information into a computer program to screen inappropriate or potentially dangerous interactions. The program has been a great tool in the practice of pharmacy. Although pharmacies have a DUR program as well, the third party carrier adds an extra dimension. They serve as a centralized database for ensuring optimal drug therapy for the patient. Where a cash customer may get past the pharmacy in some instances, when a third party is paying for the medication, it is amazing what information gets revealed.

Id.