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 Syrus

I. INTRODUCTION

For nearly three centuries, medieval Europe was stricken by the devastating forces of the Black Death. The mysterious infections caused by the plague harbored the ability to destroy all living organisms in their path. 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.” The epidemic killed about one-third the population of England and dramatically altered the social, political, and economical life of its survivors. The destructive power of

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 dysentary, diphtheria, 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.  

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. "Without a doubt, diseases as yet unknown, but with the potential to be the AIDS of tomorrow, lurk in the shadows." The battle is staged: Man vs. Microbe, in a quest for medical supremacy. 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. 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-
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 cell 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.\textsuperscript{4} In about half of these cases, the course of therapy is considered inappropriate.\textsuperscript{5} Most patients and physicians are unaware of the harmful side effects that may result from the misuse or overuse of antibiotics.\textsuperscript{6} 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.\textsuperscript{7} As a result, millions of people are unnecessarily exposed to a whole array of antibiotics which enhances bacteria's ability to evade destruction.\textsuperscript{8}

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".\textsuperscript{9} With society becoming more mobile and travel abroad becoming more popular, the possibility of a Black Death

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

\textbf{14.} \textit{Id.} The author notes that about 150 million courses of antibiotics are prescribed in the United States each year. \textit{Id. See also} Linda F. McCaig & James M. Hughes, \textit{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).

\textit{Id.} 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. \textit{Id.}

\textbf{15.} \textit{See} Gasbarro, \textit{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. \textit{Id.}

\textbf{16.} \textit{See} LEVY, \textit{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.

\textit{Id.}

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

\textbf{18.} \textit{See} LEVY, \textit{supra} note 10, at 215. The unnecessary and inappropriate use of antibiotics adds an economic burden to the health care system. \textit{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. \textit{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. \textit{Id.}

\textbf{19.} See Robert W. Pinner et al., \textit{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.\textsuperscript{20}

Although there are several medical approaches\textsuperscript{21} aimed at alleviating the strain of bacterial resistance, their effects have been negligible.\textsuperscript{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.\textsuperscript{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.

an outbreak of fatal respiratory illness in the American Southwest in 1993. \textit{Id.} Contamination of a public water supply with the parasite \textit{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. \textit{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. \textit{Id.}

\textbf{20.} See Barbara E. Mintz et al., \textit{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. \textit{Id.} See also Charles Henderson, \textit{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.” \textit{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.” \textit{Id.}

\textbf{21.} See S.K. Obaro et al., \textit{The Pneumonococcal Problem}, 312 BMJ 1521 (1996). The authors note that Streptococcus pneumonia 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. \textit{Id.} at 1527. Furthermore, one approach to this problem is to improve host protective immunity to the organism by immunization. \textit{Id.} Although, current vaccines have a good safety record, they lack efficacy. \textit{Id.}

\textbf{22.} See Leslie Alan Horvitz, \textit{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. \textit{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. \textit{Id.}

\textbf{23.} \textit{Id.} “A once formidable arsenal of antibiotics has become the medical equivalent of blunderbusses and Gatling guns.” \textit{Id.} “During the last 12 years, the mortality rate from infectious diseases has risen 58 percent.” \textit{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.” \textit{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.” \textit{Id.} at 42 (quoting Stuart Levy, Professor at Boston’s Tufts University).

Even though some hospitals have initiated programs aimed at curbing inappropriate antibiotic use, present day circumstances warrant a comprehensive approach to the pending epidemic. 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. This article sets forth the Antibiotic Resistance Epidemic in Part II. Parts III and IV discuss the causative agents while emphasizing the need for a regulatory attack to the problem. 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, while dissecting the oppositions concerns about the prohibitive measure in Part VII.

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. 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. 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 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.

25. See 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.

26. Id. “Leading microbiologist disease specialists are taking part in a conference to discuss how the spread of antibiotic resistance can be contained.” 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. 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. Moreover, what once was thought of as primarily a hospital problem is becoming a problem in the community as well. 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. In addition, various societal and technological changes that have occurred in the last decade facilitate the transmission of drug-resistant organisms. 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 pneumonia 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.\textsuperscript{37}

Although antibiotics are deemed harmless, they harness the ability to alter the future of our nation's health.\textsuperscript{38} The role of an antibiotic is to gain access within a bacterial cell.\textsuperscript{39} Once inside, the agent corrupts the processes which keep bacteria alive.\textsuperscript{40} There exist several classes of antibiotics which have unique focal points of attack against bacteria.\textsuperscript{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.\textsuperscript{42} Once a bacterial cell mutates to avoid destruction, this mode of resistance is passed on to their progeny.\textsuperscript{43} As a result, narrow spectrum antibiotics, which have a limited use to

\textsuperscript{37} See Gasbarro \textit{supra} note 11, at 54. Bacteria are becoming increasingly resistant to the antibiotics used against them which is caused through antibiotic misuse and overuse. \textit{Id.} Bacterial strains that are resistant to standard drugs have developed as a result of the continued misuse of medicines, particularly antibiotics. \textit{Id.} Antibiotic resistance has spread to a number of infectious diseases, making it an international concern. \textit{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. \textit{Id.}

\textsuperscript{38} \textit{Id.}

\textsuperscript{39} See Gasbarro, \textit{supra} note 11, at 49.

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

\textsuperscript{41} See Michelle Meyer, \textit{Antibiotics: Are They the Newest Abused Drug}, \textit{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. \textit{Id.} Antibiotic common uses: Ampicillin or Amoxicillin—middle-ear and urinary tract infections, Bactrim—urinary tract infections, Aids-related infections, diarreal infections, Biaxin—bronchitis, Legionaires disease, and sexually transmitted diseases, Cefclor—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. \textit{Id.} (relying on information by Mathew L. Lenz, M.D., Houston internist).

\textsuperscript{42} See Gelone, \textit{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. \textit{Id.}

\textsuperscript{43} See Levy, \textit{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. Therefore, physicians resort to prescribing the newer, broad spectrum agents to avoid potential resistance. 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.

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. 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. First, a major problem exists due to patient inconsistencies in seeking treatment and 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.

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. For example, some individuals will visit the doctor for any sneeze, sniffle, or cough, while others who need medical attention oftentimes do not receive it. Likewise, those patients who reap only a psychological benefit from a visit to a doctor, will leave with an unnecessary prescription. In addition, lack of patient compliance poses a serious threat. 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.
Due to physician's virtually unrestricted prescribing ability, they repre-
sent the most significant force behind the emergence of antibiotic resistance. Often, physicians rely on information supplied by sales representatives of drug companies when prescribing antibiotics. As a result, the broad spectrum, more expensive antibiotics are overprescribed. 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. Moreover, many physicians, in an effort to maximize their customer base, will succumb to the antibiotic seeking patient's demands. This result occurs notwithstanding a corresponding diagnosis which recommends alternative therapy.

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—
antibiotic resistance. 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.

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. Furthermore, the Center for Disease Control (CDC) estimates that more than half of the infection related deaths involve resistant bacteria. 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 ANTImIoric 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. 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. However, if the privilege is abused to the point of jeopardizing the health and safety of society, the license can be revoked or suspended. 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, they possess "the power of the pen" and are virtually unrestricted when it comes to prescribing antibiotics. The physician has been confined in other areas of medicine with prescribing limitations. 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 REV CODE. been confined in other areas of medicine with prescribing limitations.

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. A physician who violates the prescribing restrictions may have their license suspended or revoked.

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. 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 physician's 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 license 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. 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. A regulatory scheme will promote uniformity and enable physicians to "just say no." Another advantage to a regulatory program is the prevention of doctor shopping. 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. The regulations would also serve as an educational tool to enlighten physician and patient understanding of the extent of a potential disaster. As a result, when faced with legal regulations, physicians will be less likely to prescribe sight unseen or cause unknown. 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. The regulations will enable the insurance company to allow monetary incentives for those patients and physicians complying with the regulations. Most prescription payers already have the necessary equipment to enforce an additional restriction. The insurance companies have a drug utilization review (DUR) program which recognizes and corrects other therapeutic inadequacies. 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 KL AIS 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.
health care costs by instituting a checks and balances system in the drug therapy arena.\textsuperscript{90} In Ohio, the Ohio Administrative Code established a DUR board to review drug utilization in claims submitted to the Department of Health and Human Services.\textsuperscript{91} Although the initiative is a step in the right direction, a closer look reveals the program is largely voluntary.\textsuperscript{92} The Ohio

90. \textit{Id.} Mr. Dennis, in discussing the checks and balance system notes: "The insurance company is able to cross-reference all prescriptions they receive for payment." \textit{Id.} The pharmacist interviewed spoke on the effects of third party insurance companies on the advent of antibiotic resistance: "Within the last year, I have begun to see more drug screening in the antibiotic field." \textit{Id.} "For example, if a patient was taking an antibiotic for more than the recommended number of days for optimal treatment, the company will refuse to pay for the medicine until the pharmacist has spoken with the physician to get an explanation." \textit{Id.} "The insurance company will also refuse to pay for claims which contain a drug-drug or drug-disease state interaction." \textit{Id.} "This process is time-consuming, yet beneficial to provide optimal drug therapy." \textit{Id.}

91. A DUR (drug utilization review) program is set forth in \textsc{Ohio Administrative Code }\S\textsc{ }5101:3-9-16 (Banks-Baldwin 1996) providing for the ongoing review of claims submitted to the Department of Health and Human Services. \textsc{Ohio Administrative Code }\S\textsc{ }5101:3-9-16 states:

\begin{enumerate}
\item Membership

(1) The DUR board shall include health care professionals appointed by the director of human services, who have recognized knowledge and expertise in one or more of the following:

(a) The clinically appropriate prescribing of covered outpatient drugs;
(b) The clinically appropriate dispensing and monitoring of outpatient drugs;
(c) Drug use review, evaluation, and intervention;
(d) Medical quality assurance.

(2) The DUR board shall be comprised of four licensed and actively practicing physicians, at least one of which is a doctor of osteopathic medicine, four licensed and actively practicing pharmacists, and one nonvoting department staff person...

\item Duties.

(1) The DUR board shall review and recommend multiple levels of intervention for physicians and pharmacists targeted toward therapy problems or individuals identified in the course of retrospective drug use reviews. Intervention programs shall include, in appropriate instances at least:

Written, oral, or electronic reminders containing patient specific and/or drug specific information and suggested changes in prescribing or dispensing practices, communicated in a way to ensure the privacy of patient related information....

92. \textit{Id.} The unfavorable result referred to is the lack of enforcement power contained within the DUR board establishment. \textit{Id.} The DUR board may deter certain provider conduct, but a stronger mechanism is needed to get the point across. \textit{Id.}
Administrative Code Section 5101-3-9-16 "recommends" interventions and "reminds" the physicians and pharmacist of more appropriate therapy. This may serve as an educational tool to some practitioner's way of thinking, but a more stringent approach is needed to control their method of prescribing. The proposed antibiotic regulations will enable the third party payer to facilitate the process of health care management with the imposition of monetary controls on drug use. In the absence of such a consumer based remedy, antibiotic use will continue to thrive because someone else is footing the bill.

93. Id.
94. Telephone interview with Robert Madrigal, Registered Pharmacist in Barberton, Ohio (Feb. 10, 1997). Mr. Madrigal comments on the current DUR program:

Currently, the DUR program in Ohio may make things more difficult to fill a prescription, but overriding the intervention is not very difficult at all. Although, I pay attention to the recommendations, many other pharmacist, nurses, and physicians may just override the message without a second thought. However, if a situation were to arise where a diminution in payment is seen, such as where a program mandates generic substitution, a closer look seems to be in order. When money is involved, it may make people stop and think.

Id.

95. Id. The pharmacist interviewed spoke on the effects of third party insurance companies on the advent of antibiotic resistance: "Within the last year, I have begun to see more drug screening in the antibiotic field." Id. "For example, if a patient was taking an antibiotic for more than the recommended number of days for optimal treatment, the company will refuse to pay for the medicine until the pharmacist has spoken with the physician to get an explanation." Id. "The insurance company will also refuse to pay for claims which contain a drug-drug or drug-disease state interaction." Id. "This process is time-consuming, yet beneficial to provide optimal drug therapy." Id.

96. Telephone interview with Phillip Michael, Registered Pharmacist in Charleston, West Virginia (Jan. 10, 1997). Mr. Michael regards the antibiotic resistance problem as an epidemic already. He comments on the prescribing habits of physicians:

The classic scenario exists where a patient with prescription insurance comes into the pharmacy holding a prescription for the newest and most expensive antibiotic on the market. He or she will leave paying under ten dollars as a copayment for a drug which may cost the insurance company well over 100 dollars. After speaking with the patient, I conclude that they probably have a touch of the flu, to which antibiotics are of no avail. A second patient arrives almost simultaneously with a prescription from the same physician. However, in this case the patient does not carry prescription insurance. The prescription is written for an inexpensive narrow spectrum antibiotic. This patient, I also believe had a touch of the flu.

Id. The interviewee acknowledged that prescribing habits of physicians seemed to correspond directly with who was footing the bill. The following regulatory proposal would hinder this inappropriate prescribing cycle. Id.
V. THE POWER TO REGULATE ANTIBIOTIC PRESCRIPTIONS

The power to regulate antibiotic prescribing can be obtained from two existing regulatory schemes. First, under the Ohio Public Health Laws, a broad authority exists to maintain public health and safety. For example, in 1996, the Ohio legislature established a resolution which would impose monetary sanctions on health care practitioners for violating therapeutic treatment guidelines in certain areas. Although antibiotic prescribing restrictions are not specifically entertained by the resolution, the power to confine treatment methods in highly volatile


98. See OHIO REV CODE ANN. § 3709.22 (Banks-Baldwin 1996) which states:

Each board of health of a city or general health district shall study and record the prevalence of disease within its district and provide for the prompt diagnosis and control of communicable diseases. The board may also provide for the medical and dental supervision of school children, for the free treatment of cases of venereal diseases, for the inspection of schools, public institutions, jails, workhouses, children's homes, infirmaries, and county homes, and other charitable, benevolent, and correctional institutions.

Id. See also OHIO REV CODE ANN. § 3707.04 (Banks-Baldwin 1996) which states:

In time of epidemic or threatened epidemic, or when a dangerous communicable disease is unusually prevalent, the board of health of a city or general health district, after a personal investigation by its members or executive officer to establish the facts in the case, and not otherwise, may impose a quarantine on vessels, railroads, or other public or private vehicles conveying persons, baggage, or freight, or used for such purpose. The board may make and enforce such rules and regulations as are wise and necessary for protection of the health of the people of the community....

Id.

99. See OHIO REV CODE ANN. § 3702.11 (Banks-Baldwin 1996) which states:

The director of health shall adopt rules establishing safety standards, quality of care standards, and quality of care data reporting requirements for each of the following:

(A) Solid organ and bone marrow transplantation;
(B) Stem cell harvesting and reinfusion;
(C) Cardiac Catheterization;
(D) Open-heart surgery;
(E) Obstetric and newborn care;
(F) Pediatric intensive care;
(G) Operation of linear accelerators;
(H) Operation of cobalt radiation therapy units;
(I) Operation of gamma knives
public health areas is already in place.\textsuperscript{100}

Secondly, a more specific power to control prescribing habits is contained in the Drug Laws of Ohio.\textsuperscript{101} For example, under 4731.22 of the Ohio Revised Code, the state medical board may revoke or suspend a physician's license 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." Prescribing antibiotics on demand without utilizing proper diagnosis and therapeutic recommendations arguably falls within the realm of this statute.\textsuperscript{102} Although antibiotics have yet to be included in

100. The Ohio Revised Code grants investigative powers to seek out public health problems, see Ohio Rev Code Ann. § 3702.19 which states in part:

In investigating possible violations of § 3702.14 of the Revised Code, or in conducting hearings under § 3702.20 of the Revised Code, the director of health may administer oaths, order the taking of depositions, and issue subpoenas compelling attendance of witnesses or production of documents.

Id. The Ohio Revised Code contains a provision to monitor compliance with public health programs, see Ohio Rev Code Ann. § 3702.15 (Banks-Baldwin 1996) which states:

The director of health shall monitor health care providers for compliance with the safety and quality of care standards established in the rules adopted under § 3702.11 of the Revised Code. The director may inspect any health care provider as the director determines adequate to monitor compliance. The rules may require health care providers regularly to issue reports and undergo independent audits.

Id. Finally, an enforcement provision under the Public Health Laws of Ohio can be seen in the Ohio Rev Code Ann. § 3702.20 (Banks-Baldwin 1996) which states in part:

If the director of health determines that a person has violated § 3702.14 of the Revised Code, the director, after affording the person an opportunity for a hearing conducted in accordance with Chapter 119 of the Revised Code, shall impose a civil penalty of not less than one thousand dollars and not more than two hundred fifty thousand dollars on the person. In addition to the civil penalty, for a second or subsequent violation of § 3702.14 of the Revised Code, or for a first violation that the director determines has caused or poses an imminent threat of serious physical or life-threatening danger, the director, after affording the person an opportunity for a hearing in accordance with Chapter 119 of the Revised Code, may issue an order that the person cease operating the health service.

Id.


102. Ohio Rev Code Ann. § 4722.31(B) (Banks-Baldwin 1996) grants the state medical board authority, pursuant to adjudicatory hearings, to limit, revoke, or suspend a physician's license for: "Failure to use reasonable care discrimination in the administration of drugs, or the 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 (B) (2). Furthermore, administrative action may be taken for "selling, prescribing, giving away, or administering drugs for other than legal and legitimate therapeutics." Id. at Sec. B (3).
this regulatory arena, the imposition of medically proven and scientifically reliable antibiotic guidelines will add bite to the existing bark which underlies efforts to control the pending epidemic. As a result, under a general police power or under more specific prescribing limitations, antibiotic use guidelines are an appropriate extension of existing legislation.

VI. The Regulatory Proposal

Thus far, this article has discussed the nature of the antibiotic resistance problem, the causative agents, why there is a great need for legal regulations, and where the power to regulate antibiotic can be obtained. The following regulatory proposal is geared toward alleviating the strain of resistant organisms without compromising the quality of health care. Other regulations have been successfully administered in the hospital and managed care settings. However, a broad spectrum attack at the community level is necessary to facilitate uniformity and control. Congress and the states should adopt regulations from the following proposals.

103. See Mainous et al., supra note 51 (concluding that “a majority of persons receiving medical care... are given prescriptions for an unnecessary antibiotic. Unchecked, this practice may lead to greater antibiotic resistance and unnecessary use of health care resources. Future research should focus on the ability to institute behavioral changes... ”).

104. Id. The behavioral changes Dr. Mainous speaks of can be obtained with the use of a comprehensive regulatory strategy that will provide educational and enforcement provisions to aid in the battle against the bacterial world. Id.


Excessive and inappropriate use of antibiotics in hospitals contributes to the development of antibiotic resistance. Denver’s three major teaching hospitals have developed a multifaceted approach that has curbed inappropriate antibiotic prescribing. A joint antibiotic-use committee with representatives from each hospital’s pharmacy and therapeutics committee developed a single antibiotic formulary for systemically active bacterial agents, based on simplicity, clinical efficacy, previous use patterns, local resistance patterns, and relative cost. This formulary includes primary agents, ordered at the prescriber’s discretion; secondary agents, ordered only for an approved condition; and restricted agents which have been used excessively or inappropriately in the past, and are now dispensed only after consultation with an infectious disease specialist. Id.

106. See Cash, supra note 48 at 181. The author notes that keeping abreast of changing patterns of microbial resistance presents a formidable challenge to all those prescribing antibiotics. Id. The author adds that when national standards are developed for treating infectious diseases, recommendations must be transmitted to local practitioners and drug sellers. Id. See also Mainous et al., supra note 51. The author remarks that guidelines on the proper use of antibiotics have proven to be valuable in the hospitals and managed care settings. Id. He also states, “open systems, such as the general community of physicians, could also be influenced by clinical guidelines.... Evidence suggests that clinical guidelines for medical practice can
First, physicians should be prohibited—with certain exceptions—from prescribing antibiotics without physically observing the patient. Such exceptions might include antibiotics prescribed as a preventive measure for persons traveling to areas where an outbreak of a particular disease has occurred, or in instances where the antibiotic is being prescribed as a preoperative treatment. Other exceptions might be allowed where the physician prescribes an antibiotic to contain the spread of an infection in a closed environment. Under circumstances where physical observation is impossible or impractical, a physician may initiate antibiotic therapy with a narrow spectrum agent if the physician certifies the need for antibiotic treatment.

A certification procedure should also be established to document the need for a particular antibiotic prescription. This would require the physician to complete a standard form indicating the diagnosis and why the physician believes an antibiotic is warranted under the circumstances.

Narrow spectrum antibiotics should be regulated so that they are only pre-
scribed when a bacterial infection is diagnosed,
 the physician in her professional judgment can certify that an antibiotic is necessary to prevent the development of a complicated infection, or the patient is high risk for developing an infection.

Broad spectrum antibiotics should only be prescribed when the physician physically diagnoses a bacterial infection and the patient is high risk for developing complications from the infection, or when the patient has already concluded a narrow spectrum antibiotic regimen without improvement and the physician performs culture and sensitivity test to harmonize antibiotic selec-

113. The advisory committee, consisting of experts in health care, such as physicians, pharmacists, nurse practitioners, and infectious disease specialists, will assist the legislators in enacting guidelines to accompany this Act. The advisory committee as a diverse array of health care participants will also be responsible to assess whether a violation has occurred. For example, a bacterial diagnosis may consist of actually taking a culture and sensitivity test or if patient presents with tell tale signs and symptoms of bacterial infection.

114. See the certification procedure as outlined in text. Also, by utilizing a professional judgment standard, we leave a certain degree of prescribing autonomy with the physician and aid the arbitration board in determining if the standard of care performed was appropriate and reasonable according to the standards established as guidelines.

115. See LEVY, supra note 10, at 127. "A common prophylactic use of antibiotics is to prevent infection in patients who have had disease of the valves of the heart or have a heart murmur." Id. "The latter indicates some change in the normal functioning of the heart that may make them more susceptible to bacterial infections." Id. Also, following tooth extraction that might cause transient passage of bacteria from the mouth into the bloodstream. Id. "Antibiotics cannot prevent bacteria from entering the bloodstream, they can prevent them from 'setting up shop.'" Id. Antibiotics are not recommended for "clean" operations except where the rare chance of infection could produce drastic consequences, such as in heart surgery. Id.

116. Id. at 126. "In a sick infant suffering from fever and possible dehydration and having little body resilience, the high probability of bacterial infection warrants the use of antibiotics immediately and for the sustained period of the illness." Id. "In this case, early use of medications can be truly life-saving, but clinicians still should utilize culture and susceptibility testing to confirm that the right drug had been started." Id. In addition, an elderly, very sick patient with high fever and other signs of obvious infection is presumed to have a bacterial infection, therefore, after culturing possible sites of infection, antibiotics are begun. Id. "However, the same decision is not appropriate for an otherwise healthy, young adult who suffers from symptoms attributable to a suspected viral illness." Id. at 127.

117. A lengthy discussion on the names of medications deemed narrow spectrum and broad spectrum is inappropriate for this article. However, it is important to note that the narrow spectrum agents have selective specificity and are usually less expensive, whereas broad spectrum antibiotic are the newer agents, oftentimes adaptations of the older agents which have a broad range of attack on various bacteria. The broad spectrum agents can cost patients hundreds of dollars whereas the older agents usually run less than twenty dollars. Michael A. Misocky, Registered Pharmacist.

118. See supra note 116, for an example of diagnosing without the aid of culture and sensitivity tests.

119. See supra notes 107-118, and accompanying text. Other factors include age of patient, other disease states, and alcohol use.
tion. Another exception might be allowed where the patient has shown either resistance or an allergic reaction to the recommended narrow spectrum agents.

Any second course of broad spectrum therapy for the same ailment should only be prescribed by, or after consultation with, an infectious disease specialist, or where the treating physician performs culture and sensitivity test and certifies that the selected agent was appropriate.

The focus of regulatory action in the community will decrease the number of prescriptions phoned in without an actual office visit. This will enable a physician to physically observe the patient and provides an excellent opportunity for communication among health care participants. Regulations should aim to force both the physician and patient to undergo certain checkpoints before initiating care to ensure that proper treatment is rendered.

The regulatory goal in the hospital atmosphere is to decrease the transmission rate of resistant bacteria. The methodology proposed in this article provides a mechanism to facilitate aseptic techniques to decrease the risk of patients developing a complicated infection. Since hospitals are close quartered institu-

120. See Levy, supra note 10, at 120. The author comments on the culture and sensitivity process: “physicians obtain cultures and perform tests on different areas of the body...In the presence of a fever and soreness of the throat or difficulty swallowing, a physician may want to obtain a swab of the throat and culture it to check for a bacterial culprit, such as streptococcus, which causes strep throat.” Id. “Initially, a simple test can be done in the office...the spu-
tum sample is smeared on a glass slide that is stained for bacteria, namely by the Gram stain.” Id. at 121. In addition, all clinical specimens should go to a bacteriology laboratory where they are put into culture systems that allow growth of any microorganisms present. Id. at 122. The specimens are cultured onto a special gelatin medium in round plastic dishes. Id. If the bacteriologist finds disease-causing bacteria in these samples, the microorganism is then tested for susceptibility to antibiotics. Id at 123.

121. Id. Before our present-day problem with antibiotic resistance, simple identification of the type of bacteria causing the disease would have been enough to tell the physician which antibiotic to use. Id. Nowadays we must also determine which antibiotic is likely to be successful. Id. “The physician must always make a choice of antibiotic based on not only the susceptibility results, but also from the knowledge of possible allergies of the patient. Id. at 124. The physician should also assess the cost of medications which are effective. Id. at 125.

122. See North supra note 105, at 15 Suppl A:3-11. The author notes that the guidelines established include the requirement that drugs which have been used “excessively or inappropriately in the past, are now only dispensed after consultation with an infectious disease specialist.” Id.

123. The certification procedure as previously outlined in text, should include the culture and sensitivity results for accuracy purposes.

124. Complicated infection as defined by reasonably prudent infectious disease specialist. The risks associated with a hospital infection are greater because of the susceptibility of the strength of a patient’s immune system is diminished and the presence of communicable diseases is high.
tions, they serve as a breeding ground for bacteria. As a result, by combining a germ free operating environment with a restricted antibiotic protocol, hospitals can control the emergence of antibiotic resistance.

Enforcing the regulations proposed in this article would be a daunting task, but any such obstacles are certainly surmountable. Enforcement could be achieved by performing annual audits of physician and pharmacy records and, if necessary, imposing monetary penalties and/or suspending or revoking licenses.

125. Hospitals have a diverse patient population, each with their own unique set of problem and accompanying strains of bacteria. The typical hospital patient may be exposed to a wide variety of antibiotics, thus increasing the chances for resistant bacteria to spread via common carrier throughout the hospital.

126. The above notes and recommendations for the community apply with equal force in the hospital environment. However, this would be an excellent time to present recommendations of the Hospital Infection Control Practices Advisory Committee (HICPAC) for preventing the spread of Vancomycin resistance. See Recommendations for Preventing the Spread of Vancomycin Resistance, 44 MMWR 1, Sep. 22, 1995. The recommendations include: prudent vancomycin use by clinicians and immediate implementation of appropriate infection-control measures to prevent person-to-person transmission of vancomycin resistant enterococci (VRE). Id. at 8. The guidelines for preventing the patient-to-patient transmission of VRE:

1. Place VRE infected or colonized patients in private rooms or in the same room as other VRE infected patients.
2. Wear gloves when entering the room of a VRE infected patient because VRE can extensively contaminate such an environment.
3. Wear a gown when entering a VRE infected patient's room if a) substantial contact with the patient or environmental surfaces is anticipated, b) if the patient is incontinent, c) if the patient has had an ileostomy or colostomy, has diarrhea or wound drainage.
4. Remove gloves and gown before leaving patient's room and immediately wash with a antiseptic soap or waterless antiseptic agent.
5. Ensure that after glove and gown removal and handwashing, clothing and hands do not contact environmental surfaces in the patient's room.

Guidelines for appropriate use:

1. Treatment of serious infections caused by beta-lactam resistant gram positive organisms.
2. For treatment of infections caused by gram-positive microorganisms in patients who have serious allergies to beta-lactam antibiotics.
3. When antibiotic associated colitis fails to respond to metronidazole therapy or is severe or potentially life-threatening.
4. Prophylaxis, as recommended by the American Heart Association, for endocarditis following certain procedures for patients at high-risk for endocarditis.
5. Prophylaxis for major surgical procedures involving implantation of prosthetic materials at institutions with a high rate of infections caused by MRSA. Prophylaxis should be discontinued after a maximum of two doses.

128. The enforcement mechanism is vital to the success of regulations. By placing con-
Pharmacists could be the first line of defense in an enforcement model. They could be required to report violations if, after consultation with the prescribing physician and patient, they can verify violations to the appropriate agency responsible for enforcement. Moreover, pharmacists should be empowered to refuse to fill prescriptions when doing so would be a violation of applicable regulations.

Third party payers also have a role to play in enforcement. Such entities could be required to initiate and maintain a drug utilization review program aimed at restricting inappropriate antibiotic use. Third party payers could induce compliance with their review programs by utilizing monetary incentives or restrictions with both patients and physicians. Third party payers could also be

trol of implementation in the hands of the states, much like the EPA has done with various regulations, you ensure that state sovereignty is not infringed upon while necessitating the a uniform approach to the problem. Imposing various monetary fines and/or suspension/revocation of licenses will coerce changes among practitioner’s prescribing habits. The physician will be served with a wake up call to acknowledge to existence of a pending epidemic. The audits of physician and pharmacy records already have been conducted by the State Boards of Pharmacy and Medicine concerning other violations of state/federal laws.

129. The certification procedure as described above with apply with equal merit here. The pharmacist may be supplied with forms to be filled out when a violation occurs. The proper investigation can then ensue. The certification should provide the nature of the violation and include any appropriate discussions with the patient and/or physician. The pharmacist currently serves as gatekeeper in other overlapping areas of medicine and the law. As a drug therapy expert, this power is not wrongly bestowed.

130. A pharmacist has the ability to refuse to fill a prescription which, in their professional judgment is inappropriate or illegitimate. By incorporating legal regulations on antibiotic prescribing, this will provide additional backing to enable the pharmacist to provide quality therapeutic care in an area in great need of rehabilitation. See generally, C. Klem & J. Dasta, Efforts of Pharmacy To Reduce Antibiotic Resistance, NEW HORIZ, Aug. 1996. The authors note that pharmacists have an integral role in the care of patients with infections. Id. Antibiotics continue to be among the most commonly prescribed drugs. Id. The authors note that numerous studies point to inappropriate antibiotic use and resultant selective pressure on antimicrobial resistance. Id. The pharmacist can impact this prescribing by assuring optimal pharmacotherapy specific for the organism and associated disease. Id. Finally, the authors note that future research is needed to determine the optimal method for preventing resistance, but add that a multidisciplinary approach is suggested. Id.

131. Likewise, in order to properly control the conduct of both consumers and physicians, an economic remedy from third party insurance companies, if properly administered, can serve as a great incentive. A patient already has seen the impacts of managed care. The patient is usually restricted on whom they may seek care or face increased out-of-pocket expenses. Likewise, when faced with a therapeutically beneficial decision to forego an expensive antibiotic for a less expensive one, the decision may be quite easy if a patient is forced to bear the costs of an inappropriate antibiotic. In addition, physicians rely heavily on insurance companies for payment of services rendered. It would be conducive to their profit margin to abide by the regulations when faced with the imposition of monetary penalties for inappropriate prescribing of antibiotics. The average third party payer will face little or no additional cost to implement an additional therapeutic intervention onto their existing DUR programs. The money saved as a result will surely pay for itself, and the consumer, who will be better off medically, may also reap an economic kickback in the form of reduced premiums.
authorized to conduct audits of pharmacies and physicians to assist them in complying with applicable regulations. They could also be permitted to establish a payment arrangement where the payer can withhold payment for services rendered in violation of applicable regulations. Such payment disputes could be handled by an informal "arbitration board" established by the appropriate enforcement agency.

Although the foregoing proposal is only a starting point for complex legislation, the proposal can serve as a solid foundation upon which legislators can build a comprehensive regulatory action. For example, the proposal fails to mention drug manufacturers. However, potential legislation including the drug manufacturers may include a tax subsidy for the development of new antibiotics, a limitation placed on free samples to be distributed to physicians, and a possi-

132. The arbitration board shall be established in the form of a judiciary to preside over conflicting views among consumers, providers, and payers resulting from these regulations. As experts in the health care arena, they will be able to properly convey their knowledge to the parties, and make a decision which is based in the interests of public health.

133. See Horvitz, supra note 22, at 5. "[T]he congressional Office of Technology and Assessment (which recently was eliminated by Congress) issued a report calling on the government to provide pharmaceutical companies with tax incentives to encourage research on new drugs. But...no action has been taken to institute its recommendations." Id.

134. The current restraints on drug samples are not restraints at all, but merely procedural requirements. See 21 U.S.C.A. § 353 (d) which states:

(2)(A) The manufacturer or authorized distributor of record of a drug subject to subsection (b) of this section may, in accordance with this paragraph, distribute drug samples by mail or common carrier to practitioners licensed, to prescribe such drugs or, at the request of a licensed practitioner to pharmacies of hospitals or other health care entities. Such a distribution of drug samples may only be made—

(i) in response to a written request for drug samples made on a form which meets the (B), and

(ii) under a system which requires the recipient of the drug sample to execute a written receipt for the drug sample upon its delivery and the return of the receipt to the manufacturer or authorized distributor of record.

(B) A written request for a drug sample required by subparagraph (A) (i) shall contain—

(i) the name, address, professional designation, and signature of practitioner making the request,

(ii) the identity of the drug sample requested and the quantity requested,

(iii) the name of the manufacturer of the drug sample requested, and

(iv) the date of the request.

21 U.S.C. § 353 (d) (1995). A better approach would be to limit the maximum number of drug samples which can be distributed. Also, restricting samples of new broad spectrum antibiotics to physicians who can document the therapeutic need for such agent would prove more beneficial. Another problem that sample distribution causes is inadequate course of therapy.
ble accelerated approval time for antibiotics which can be used on a limited basis in emergency situations. Any law ultimately enacted to combat the problem of antibiotic resistance should strive for a symbiotic relationship between the regulatory process and our health care system. The proposal includes a communication ingredient, as well as, an enforcement mechanism to launch an effective attack on the spread of infectious disease. Although the proposal tailors to a health and safety objective, hurdles still need to be crossed and obstacles cleared to ease the rough terrain that patients, health practitioners, and industry may resurrect.

VII. Probable Objections

The regulatory process rarely finds favor with all whom it affects. In this regard, arguments against the proposal will arise from patients, providers, and drug manufacturers. Patients will likely object because the regulations may encroach on their perceived wellness. A patient will have a difficult time understanding “no” and therefore attempt to seek out another provider to obtain the

For example, pharmacists have suggested that because a broad spectrum antibiotic is so expensive, patients will be less likely to get a full prescription and rely on the sample quantity instead. This practice yields harmful results and only aggravates the resistance problem because the bacteria will be able to view the antibiotic without being terminated. Telephone interview with Michael Dennis, Registered Pharmacist (Jan. 22, 1997).

135. See generally, Accelerated approval with restricted access could be one option for handling emerging antibiotic resistance, F-D-C REPORTS PRESCRIPTIONPHARMACEUTICALS AND BIOTECHNOLOGY, July 29, 1996. The FDA Office of Drug Evaluation reports that making antibiotics a class drug or controlled substance would be another approach. Id. This approach would be consistent with the high psychological abuse potential of antibiotics. Id.

136. The answer to the antibiotic resistance epidemic lies in the ability of government and industry to cooperate in an effort to stop the spread of infectious diseases. See generally Joshua Lederberg, Infection Emergent, JAMA, Jan. 17, 1996 (noting that there is a need for a government-industry cooperative to respond quickly in the event of a pandemic).

137. The existing legislation in Ohio provides a DUR (drug utilization review) mechanism for claims submitted to Department of Human Services, see supra note 86, but only “recommends” or “reminds” the practitioner of therapeutic guidelines, thus containing a communication ingredient but lacking an enforcement mechanism. See supra notes 86-87 and accompanying text. Likewise, the public health laws and drug laws of Ohio contain the necessary enforcement ingredient for violations but lack the communication which is essential to compliance. See supra notes 96-97 and accompanying text. The proposal in this article combines the two essential ingredients into one complex remedy aimed at alleviating the strain of antibiotic resistance.

138. For a general discussion on the problems associated with imposing regulations in the health care field, see infra notes 140-163, and accompanying text.

139. See infra notes 140-163, and accompanying text.

140. See Meyer, supra note 41. “Nearly one-fourth of Americans misuse antibiotics—and that's one reason meningitis, tuberculosis, and other diseases medicine once felled are now more virulent than ever.” Id. “70 percent of patients surveyed asked their doctors for antibiotics to treat viruses, against which the drugs are useless.” Id. See also Mainous et al., supra note 51, at 357. “Even though there is no cure for the common cold, physicians may still pre-
antibiotics. However, the regulatory proposal seeks to impose uniform restrictions on all providers which will diminish doctor shopping among patients. Furthermore, patients may not understand that sacrificing their desires now will ensure the future health of our nation. This concern will hopefully be addressed by the integrity underlying the patient/physician relationship.

A typical patient focuses on the isolation of an event without taking into account the aggregate effects. For example a patient response might yield, "I am only one person, how could I possibly cause an epidemic?" This common thought process involves the problem of externalities, where an individual seeks to minimize internal costs by allocating them to the entire population. For exam-
ple, patients are less likely to take precautionary measures when the ill-effects are dispersed among all health care participants. However, since the proposed regulation encompasses a monetary stimulus, individual patients will find the costs associated with antibiotic misuse hitting closer to home. Moreover, the federal government has regulated individual conduct in the past when it presented a national concern analyzing the aggregate effects. Therefore, it is necessary in our proposal to regulate individual conduct when the cumulative effects may jeopardize the health of our nation.

Although many physicians would acknowledge the existence of a problem, few will take the blame. Thus, a physician will express discontent with a regulatory proposal. After approximately twelve years of post high school education, physicians may have a valid reason to disapprove of yet another infringement on their prescribing autonomy. Along these lines, our nation requires a demanding medical education and subsequently the granting of a license before entrusting internalized or placed on the victim. In the health care arena, individual patients with insurance, who receive unwarranted antibiotics, externalize their costs by raising insurance premiums for all members of a group. Thus, implementing monetary incentives to restrict antibiotic misuse, will help centralize unnecessary costs back to the patient. See e.g., Wickard v. Filburn, 317 U.S. 111 (1942) (holding that Congress may properly have considered that the individual farmer’s own contribution to the demand for wheat may be trivial by itself is not enough to remove it from the scope of federal regulation where, as here, his contribution taken together with those similarly situated, is far from trivial).

For a description of how bad things could get without a halt on the overuse of antibiotics, see Nichols, supra note 46. The author notes:

How bad could it get? Terrifyingly bad, if the rapidly reproducing and mutating microbes continue to find ways of outfoxing medicine’s battery of antibiotics. There would be nothing to stop some children’s ear infections, for instance, from turning into life-threatening meningitis, and cases of pneumonia that are now routinely treated could instead become routinely fatal. Already, drug resistance is plaguing North American hospitals and the new bugs are making it harder for doctors to treat once easy-to-cure infections.

The author adds that “if the number and variety of drug-resistant bacteria continue to proliferate, running out of antibiotics could become a real possibility.” (quoting Dr. Stephen Vas, a University of Toronto microbiologist).

Although many physicians who underscore the nature of the problem will likely object to an infringement on their prescribing autonomy, other physicians will welcome an administrative resolution to the problem. For additional commentary on why legal regulations are needed, see Nichols, supra note 144. The author asks “Do we need to put some kind of controls on what doctor’s can prescribe?” at 40. The author remarks that controls “would be something that doctors and their patients, would be certain to resent…. But it could be just one of the measures up for consideration if the microbial world continues to make progress in its relentless war with modern medicine.” Nichols comments on the prescribing mentality of
physicians with the health and safety of our people.\textsuperscript{151} As previously mentioned, physician prescribing autonomy is not absolute.\textsuperscript{152} In fact, the field of medicine is heavily regulated to promote the wellness of society.\textsuperscript{153} Furthermore, some physicians may leap at an opportunity to “just say no” without fear of compromising patient satisfaction.\textsuperscript{154} As a result, regulations are necessary to halt the inappropriate use of antibiotics and to preserve the integrity of our nation’s health care system.\textsuperscript{155}

Finally, after billions of dollars in research and development costs, drug manufacturers will most likely lobby against a regulatory program.\textsuperscript{156} Since it takes nearly fourteen years for a drug to reach the market, the manufacturers adamantly promote the sale of new medications in order to recoup costs.\textsuperscript{157} Additionally, they will complain that the imposition of regulations will result in a “catch-22” situation.\textsuperscript{158} They will assert that restricting the manufacturers ability to recoup costs will only accelerate the problem by forcing a corresponding decrease in the development of new antibiotics.\textsuperscript{159} However, as this article recom-

some physicians: “Well, it can’t do any harm—might as well start them on antibiotics.... Now we are seeing the consequences of this.” \textit{Id.} at 42. “Experts say that prescribing antibiotics has become so automatic that many doctors do not even bother to determine first if an illness is viral—in which case antibiotics are ineffective—or bacterial in origin.” \textit{Id.}

\textsuperscript{151} \textit{See generally} Ohio Revised Code Physician license application requirements. Ohio Revised Code Sec. 4730 (Banks-Baldwin 1996).

\textsuperscript{152} \textit{See generally} Ohio Revised Code, \textit{supra} note 74 and accompanying text for a discussion on the prescribing limitations on physicians.

\textsuperscript{153} \textit{Id.}

\textsuperscript{154} \textit{See generally} Hamm et al., \textit{supra} note 24. The author comments on a patient’s absolute insistence on antibiotic treatment. \textit{Id.} The author highlights a patient’s willingness to seek out another provider, who will supply them with their necessary fix. \textit{Id.}

\textsuperscript{155} \textit{Id.} “Today’s crisis over drug resistance is the product of a competition that has raged for the past half-century between disease causing bacteria and the modern, man-made agents designed to combat them.” \textit{Id.} The author remarks on the current problem: “What is clear is that widespread overuse of antibiotics provides an ideal breeding ground for mutant bacteria that can threaten human life: the more antibiotics are used, the more opportunity bacteria have to develop invulnerability—and pass that talent on to other bugs.” \textit{Id.}

\textsuperscript{156} See Donald A. Goldmann, et al., \textit{Strategies to Prevent and Control the Emergence and Spread of Antimicrobial- resistant Microorganisms in Hospitals: a Challenge to Hospital Leadership}, JAMA, Jan. 17, 1996, at 234. “Faced with this erosion in the efficacy of even the newest antimicrobials, clinicians have relied increasingly on the ability of the pharmaceutical industry to develop novel agents. However, the costs of discovering, developing, testing, and approving antimicrobials continue to escalate while the hazards of unexpected toxicity and clinical failure remain.” \textit{Id.} at 235.

\textsuperscript{157} For a discussion with a sales representative for a drug company, \textit{see infra} note 159.

\textsuperscript{158} \textit{See} Goldmann, et al, \textit{supra} note 158 at 235. Moreover, with rapid emergence of resistance, the incentive to develop new antimicrobials diminishes as the projected useful life span of these agents declines. “The bottom line is that industry is finding it increasingly difficult to keep pace with antimicrobial resistance...” \textit{Id.} \textit{See also} Horvitz, \textit{supra} note 22 at 38. “Major drug manufacturers have abandoned the development of antibiotics almost entirely. The rea-
mends, the legislature may include a tax subsidy or accelerated approval provision to counteract the monetary losses attributed to the regulations.160

Many taxpayers will express disapproval because regulatory agencies need funding to be successful.161 A typical question would be, "How can we afford to pay for this?" However, how can we afford not to?162 In reality, the reg-

son, not surprisingly, is economics. "Drug companies concentrated on cardiovasculars and abandoned infectious diseases. Patients given cardiovascular medications, such as beta blockers will take it 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.

159. Telephone Interview with Dennis Lee, Sales Representative, Zeneca Pharmaceuticals in Akron, Ohio, (Feb. 10, 1997). Mr. Lee states that "we are at a disadvantage starting out, because after millions of dollars in research and development costs, and a number of years invested, it is difficult to explain why the medicine costs so much." Id. Mr. Lee adds, "when calling on a physician's office, we promote our product as the newest and best available treatment for a particular disease, we will leave drug samples, and generally, we just try to push the sale of our product." Id. The drug manufacturers want to recoup research and development costs within the first 2-3 years after it reaches the market because the possibility new products will come out and take control of the market or in the alternative a patent will run out and a generic drug will be available. It is common knowledge among members in the drug industry that profits directly correspond with the number of prescription that are being written for your product. In the coming years, this poses an incredible obstacle to the imposition of regulations on antibiotic prescribing, however, given the right monetary incentives, the price for health can usually be achieved. See Sheridan, supra note 7 at 41. The author comments on the clout of pharmaceutical companies:

Scientists have been aware for 20 years that bacteria have been breaching the bulwarks. Long before the WHO report, individuals and interested bodies were calling for tighter controls on the dispensing of antibiotics But anyone seeking change in this area is also tangling with the marketing might, money, and global power of the pharmaceutical companies for whom antibiotics have been a license to print money.

Id. "[W]hen the U.S. National Institutes of Health attempted a global initiative in the mid-1980's designed to stop antibiotic misuse, their work was thwarted by a number of major pharmaceutical companies able to put pressure on the White House." Id. 160. Despite the relatively short half-life of antibiotics because of resistance, the drug companies are still pursuing the development of new entities. See Industry Focuses on Superbugs, PHARMACEUTICAL BUSINESS NEWS, Nov. 21, 1996. The authors notes generally that bacteria which are immune to drug therapy is creating a challenge for the pharmaceutical industry and the WHO (World Health Organization). Id. The development of a drug able to fight the resistant strains could be worth a least $1 billion dollars in annual sales for the manufacturer. Id.

161. However, with time, the cost of regulation will more than pay for itself in health care savings, due to a decline in the rate of infectious diseases. 162. See Sheridan, supra note 7. The author states that "You could of course be highly socially responsible and/or lucky and manage to avoid antibiotics all your life. But you could still become ill with disease caused by a super-bug merely through breathing the same air in theaters and shopping centers as people who have developed drug-resistant bacteria. No one is safe anymore, says WHO: 'We are standing on the brink of a global crisis in infectious disease. No country is safe from them. No country can any longer afford to ignore their threat.'" Id.
ulatory proposal, if properly carried out, will add funds to the treasury due to a sharp decline in the cost of treatment for infectious diseases.\textsuperscript{163}

VIII. CONCLUSION

As we move into the next millennium, where will we stand in the battle against bacteria? The answer to this question revolves around either putting things off until a national crisis occurs or meeting antibiotic resistance head on to thwart the progression of the inevitable. This article sets forth guidelines for regulatory action to allow our lawmakers to formulate a comprehensive attack on antibiotic resistance. If properly enforced, this proposal harnesses the ability to lower health care costs without compromising optimal therapeutics in the treatment of infectious diseases.

As the last line of defense falls prey to bacteria's uncanny ability to resist destruction, we are faced with a pending epidemic to which there may be no cure. The lack of new antibiotics in the near future, the misuse and overuse of current antibiotics, and society's nonchalant attitude toward antibiotic resistance sets the stage for the emergence of a "superbug" dictator.

Antibiotics still remain a vital instrumentality in the treatment of infectious diseases and this article in no way suggests we should abandon this method of treatment. However, we are at a time where overkill becomes more than a descriptive term. The more we become accustomed to the "miracle drug" and its plethora of benefits, the sooner we will find ourselves caught in the crossfire of antibiotic resistance. Although a voluntary remedial effort is ideal, the competitive nature of society mandates that a restrictive regime is necessary to keep a few bad apples from infecting the whole tree.

The regulatory proposal encompasses the necessary schematics to attack the interposing problem on three fronts. The proposal will allay public misconception about the power of antibiotics. In addition, a uniform approach will restrict physician's polypharmacy tendencies and hinder the "revolving door" treatment method. Finally, drug manufacturers will applaud the potential profit margin increase seen as a result of restricting the use of highly-susceptible antibiotics.

\textsuperscript{163} See Horvitz, \textit{supra} note 22, at 38. "During the last 12 years, the rate of mortality from infectious diseases has risen 58 percent, becoming the third-leading killer of Americans. Furthermore, the Centers for Disease Control and Prevention, or CDC, estimates that more than half of the 60,000 to 80,000 infection-related deaths involve resistant bacteria."
A possible approach for complex legislation might include a trial regulatory period for an isolated class of persons. For example, a state may show a compelling state interest exists in maintaining the health of Medicaid patients and initiate the regulatory proposal in a limited fashion. Then, after a significant health benefit is actuated, the regulations may be broadened to include the entire patient/physician population.

This article has recognized the existence of a significant health threat and the availability of a legal remedy to reduce the threat of antibiotic resistance. The Black Death tormented Europe for nearly three centuries before a legal remedy was introduced. It is time to heed the message dictated by our predecessor’s mistakes and halt the progression of the “superbug” epidemic. By initiating a regulatory action in the infectious disease arena, we reaffirm the strength of our democratic processes and preserve the vitality of our nation’s health care system.

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