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Just Say No: The Cipro Craze and Managed Care - Applying the Hand Formula to Managed Care Decisions

Daniel L. Freidlin

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NOTE

JUST SAY NO: THE CIPRO CRAZE AND MANAGED CARE—APPLYING THE HAND FORMULA TO MANAGED CARE DECISIONS

I. INTRODUCTION

September 11, 2001, marked a new era in world history and in the way freedom is defined in the United States. It was a day that saw hijacked commercial jetliners strike each of the Twin Towers and the Pentagon. It was a day that saw the Twin Towers, symbolic monuments of American economic prosperity, crumble to the ground. It was a day in which the terrorist network led by radical militant Osama bin Laden effectively declared war on the free world, specifically the United States and its allies.

1. See N.R. Kleinfield, A Creeping Horror: Buildings Burn and Fall as Onlookers Search for Elusive Safety, N.Y. TIMES, Sept. 12, 2001, at A1 (describing the day of terror that engulfed New York, Washington, and the world as a coordinated terrorist attack was carried out in the United States). After the first plane hit One World Trade Center, many government officials first believed that this was merely an accident of a commercial airliner gone astray. See Glen Johnson, US Troops are Put on Highest Alert, BOSTON GLOBE, Sept. 12, 2001, at A10. When the second of the Twin Towers was struck eighteen minutes later, it was apparent that this was an act of terrorism. See id.

2. See Kleinfield, supra note 1.

3. See id.

4. See Alison Mitchell & Philip Shenon, Agreement on $40 Million for Aid and a Response, N.Y. TIMES, Sept. 14, 2001, at A19. While the United States was eager to punish those responsible for the attacks, the identity of the culprit was uncertain in the early aftermath. See id. Senator John B. Breaux acknowledged “[t]here was almost unanimity that we want to go after whoever was responsible.” Id. The problem faced was that “you can’t just go off and declare war when you don’t know who you are declaring war against.” Id. Within weeks, American officials came public and stated that there is credible evidence to believe that Osama bin Laden’s al Qaeda network coordinated the attack. See Vernon Loeb & Charles Lane, U.S. Unsure on Going Public With Proof: Protecting Intelligence Sources, Methods at Issue in Case Against Bin Laden, WASH. POST, Sept. 25, 2001, at A12. In the months directly following the attacks, a series of government releases made public evidence directly linking bin Laden to the attacks, culminating in a video release in which bin Laden spoke of having knowledge of the attacks prior to September 11, 2001. See James Risen, A Gaunt bin Laden on New Tape, N.Y. TIMES, Dec. 27, 2001, at A1.
On October 7, 2001, the United States struck back, officially acting upon its declaration of war on terrorism. While explosions could be heard in the Afghan cities of Kabul, Islamabad, and Kandahar, the United States was on edge after the Federal Bureau of Investigation ("FBI") issued alerts that new terror attacks could loom ahead. The possibility that these new attacks could take the face of bioterrorism surfaced as rare cases of inhalation anthrax were reported in Florida. While the FBI is leaning towards the possibility that these new attacks were carried out by an American loner with an agenda, it is not denied that the terrorist attacks of September 11, 2001, have left the nation vulnerable enough to allow for the biological attacks. Within three weeks of the first signs of anthrax infection surfacing in early October


6. See Edward Cody, Taliban Claims Large Civilian Casualties: Afghan Rulers Increase Efforts to Win Support From Islamic World, WASH. POST, Oct. 12, 2001, at A23. The United States did not limit its attacks to Osama bin Laden and his al Qaeda network, but also targeted the ruling Taliban government of Afghanistan. See id. (describing that the attacks were also directed at Taliban strongholds within Afghanistan). Afghanistan, which has housed Osama bin Laden since his exile from Saudi Arabia, was the target of attacks because they are a nation "that 'feed (and) house' terrorists." Paul West, President Finds Unity in Shift of Priorities: Bush Vows to End Threat of Terrorism: Long Struggle Looms: Terrorism Strikes America, BALTIMORE SUN, Sept. 16, 2001, at 1A; see also Robert D. McFadden, Bin Laden's Journey from Rich, Pious Boy to the Mask of Evil, N.Y. TIMES, Sept. 30, 2001, at B5 (describing the path of Osama bin Laden from Saudi exile to terrorist leader).


8. See John-Thor Dahlburg, U.S Strikes Back: The Biological Threat: 2nd Man Exposed to Anthrax, L.A. TIMES, Oct. 9, 2001, at A1 (quoting Attorney General John Ashcroft as stating "we don’t have enough information to know whether this could be related to terrorism or not."). Although "[s]ome members of Congress are convinced" that the anthrax attacks are attributable to "Middle Eastern terrorists, intent on following up on the horror of [September] 11," many others believe that the wave of anthrax poisonings are the doings of "homegrown hate groups" preying on the vulnerability of the nation after September 11, 2001. See, e.g., Nicole Sterghos Brochu, Anthrax Suspects? Your Guess is as Good as FBI's, SUN-SENTINEL (Fort Lauderdale, FL), Nov. 15, 2001, at 23A.

9. See Brochu, supra note 8.

2001 in two employees of Florida-based media firm, American Media, traces of the bacteria surfaced at the office of then-Senate majority leader Tom Daschle, mail rooms of various media outlets in New York, and postal facilities in Washington, Florida, New York and New Jersey. The unprecedented outbreak of anthrax created a spike in the demand for the antibiotic Cipro. Cipro, a quinolone-base antibiotic developed and patented by Bayer pharmaceuticals is the most highly recognized treatment for and prophylactic agent against anthrax infection.

This war, initiated by the deadly attacks of September 11, 2001, has raised the question of whether Managed Care Organizations ("MCOs"), which provide medical insurance coverage, should pay for doses of Cipro used for prophylactic purposes when the intended recipient of the infection vary depending on which form of the bacteria the infected person contracts. See id. Early treatment is important for recovery in all forms. See id. Patients with the skin form of anthrax will die twenty percent of the time without antibiotic treatment, but with treatment, the fatality rate drops to less than one percent. See id. Patients untreated with the gastrointestinal form of anthrax have a fatality rate of twenty-five to sixty percent. See id. There is insufficient data to calculate a fatality rate for gastrointestinal anthrax with early antibiotic treatment but based on the success rate associated with the skin form of anthrax, we could assume that the fatality rate would drop significantly. See id. The most troublesome form of the disease is inhalation anthrax. See id. Early data compiled by the Centers for Disease Control ("CDC") are insufficient to calculate a fatality rate for this rare form of the disease, but it is postulated that the rate is extremely high even with antibiotic treatment. See id. As of November 1, 2001, of the ten cases of inhalation anthrax within the United States, there have been four deaths. See CDC Confirmed Cases of Anthrax, http://www.bt.cdc.gov/DocumentsApp/Anthrax/11012001/11012001noon.asp (last visited Mar. 26, 2002). While this small sample may not be enough to contradict past data, the current forty percent fatality rate is more promising than early medical literature that suggests a ninety percent fatality rate. See Center for Civilian Biodefense Strategies, Anthrax Fact Sheet 1999, at http://www.hopkins-biodefense.org/pages/agents/agentanthrax.html (last visited Mar. 26, 2002).


12. See Tamar Lewin, Bioterrorism and Anxiety are Swelling Prescriptions, N.Y. TIMES, Nov. 1, 2001, at B10 (reporting that following the first reported case of anthrax in Boca Raton, Florida, prescriptions for the antibiotic Cipro were up sixteen percent nationwide and seventy-three percent in New York). Interestingly, prescriptions for antidepressants increased by five percent in early October 2001. See id.

antibiotic is yet to be exposed to anthrax. While the question may be new with regard to Cipro treatment, the question of "preventative medicine" certainly is not.14

Further, another battle continues within the walls of Congress—specifically over the Patients’ Bill of Rights, which would allow health insurance consumers to sidestep the Employee Retirement Income Security Act of 1974 ("ERISA") thereby allowing them to sue their MCOs for malpractice.15 This battle rages on as the House of Representatives and the Senate continue to agree to disagree on the extent that patients will be protected from their MCOs.16 The ultimate passage17 of the Patients’ Bill of Rights will open the door for unprecedented litigation and leave the judiciary asking how an MCO’s decision regarding patients’ treatment is to be scrutinized and exactly what health insurance malpractice is.

Part II of this Note discusses the Managed Care model, and how it came to change the American health care system. Part III argues that most medicine is preventative and that there is little distinction between preventative and curative medicine, contrary to what MCOs would like us to believe. Part IV recommends a reasonableness standard be used when judging MCO treatment decisions. Part V discusses ERISA and how it came to bar plaintiffs from suing their MCOs. Part VI discusses the Patients’ Bill of Rights and the steps that some individual states have taken to protect their citizens. Part VII applies the reasonableness standard to the prophylactic use of Cipro and concludes that such use should not be insured by MCOs unless the patient has actually been exposed to anthrax. Part VIII discusses the role that the Provider plays in the Managed Care modality.

14. See Peter McKenna, Managed Care: Failed Experiment or Needed Cost-Cutter?, INVESTOR’S BUS. DAILY, Sept. 24, 1999, at B2 (describing the managed care system and whether or not the philosophy of preventative medicine actually decreases costs).
16. See id. Members of both the House of Representatives and the Senate are eager to pass a Patients’ Bill of Rights, but have been unable to agree on the details. See e.g., 146 CONG. REC. H 12012 (daily ed. Dec. 5, 2000) (statements of Speaker pro tempore Mr. LaToyette). President George W. Bush, who during his tenure as Governor of Texas “enacted one of the most comprehensive patient protection laws in the Nation,” strives for a similar result. Id.
17. This Note assumes that the Patients’ Bill of Rights will ultimately be passed through Congress.
II. THE RISE OF MANAGED CARE

The dynamics of health insurance have transformed since the 1930s when only one out of thirty-five employees was insured for non-work related illnesses. At that time, ninety-seven percent of the work force was medically uninsured. Traditionally, the individual paid a fee-for-service to the medical professional that rendered the care for that individual. There was no insurer to act as a middleman between the medical provider and the patient. The birth of Blue Cross hospital insurance in the 1930s was the beginning of a popular trend towards insuring health care. In 1939, the Michigan State Medical Society initiated a plan to insure the costs of surgeons and other specialist care offered in hospitals. This marked the beginning of the Blue Shield plan that enrolled fifteen million members by 1950 and fifty-six million by 1962. Although the early insurance plans limited coverage to employees, by the late 1940s, sole proprietors and those employees who were not offered insurance coverage through their employers, were given the option of purchasing individual policies. Within forty years of the original Blue Cross hospital plan, some sort of insurance policy covered seventy-four percent of individuals. A quick glance at the statistics may suggest that the problem of health insurance was solved, but a deeper look tells an opposite tale; those with health insurance found that their plans had numerous limitations and restrictions and a

18. See CHARLES ANDREWS, PROFIT FEVER: THE DRIVE TO CORPORATIZE HEALTH CARE AND HOW TO STOP IT 3 (1995) (citing a 1930 study which “found that only one million of 35 million workers had any [medical] coverage for nonoccupational ailments”).
19. See id. Recognizing this problem, on January 1, 1930, Baylor University Hospital offered public school teachers limited coverage, where in exchange for six dollars per year they would be entitled to three weeks of physician ordered hospitalization. See id. The plan was created after the hospital found that many of its outstanding bills were from delinquent teachers. See id. The plan was extremely popular, and by the year 1935, there were 23,000 enrollees. See id. Within two years of the initiation of the Baylor University Hospital plan, seven other nonprofit hospitals in Sacramento, California created comparable plans. See id. There was however a difference that made the new plans resemble the managed care system as we know it today; the California hospitals created a separate “nonprofit health insurance company to administer their plan.” Id.
20. See id. at 4.
21. See id. at 3.
22. See id. at 4.
23. See id. at 5.
24. See id.
25. See id. at 6 (discussing that with the commercialization of insurance, companies sold forty million individual policies).
26. See id. at 7. By 1961, there were eight hundred commercial insurance companies marked by restrictions and limitations that were uncharacteristic of the original Blue Cross plans. See id. at 6.
majority of the elderly, who represent a majority of the billions of dollars spent on health care, were uninsured. In addition, advancements in medical technology added a new problem to the mix: rising costs.

There have been numerous culprits named for the rapid, extensive rise in the cost of health care. Already mentioned is the unusual phenomenon referred to as the "paradox of medical technology." A second factor leading to increased costs of care was the fee-for-service model of health care. Along those lines, the fee-for-service model also encouraged physicians to practice defensive medicine. Defensive medicine is the practice by which "the impetus for ordering additional tests and procedures is not primarily to benefit the patient but, rather, to reduce the prescribing physician's exposure to malpractice liability risk." The practice of defensive medicine by a physician does not take into account the externalities of rising health care costs. Defensive medicine found physicians selfishly overtreating patients in order to

27. See id. at 7. While the problem of the uninsured may seem to have been solved, the statistics were very deceiving. The exclusions and limitations of these insurance plans left many medical bills unpaid and the beneficiaries of the plans wondering where their insurance went. See id. To make matters worse, sixty-six percent of senior citizens aged sixty-five and over were uninsured. See id. A discussion of Medicare, the solution for the elderly, would encompass an entire scholarly article and is beyond the scope of this Note.


29. See Malinowski, supra note 28, at 341; see also Gonzalez, supra note 28, at 722 (stating that "[a]dvances in medical technology and their use partially account for the rising costs of medicine").

30. See Sharon Reece, The Circuitous Journey to the Patients' Bill of Rights: Winners and Losers, 65 ALB. L. REV. 17, 23 (2001) (stating that the fee-for-service model of health care was criticized "as a significant contributor to the rise in health care costs"). The fee-for-service arrangement provides a fee to be paid to the health care provider "for each service provided either directly by the insurance company or directly by the patient and reimbursed by the insurance company." Id. at 22. The fee paid to the health care provider was proportionate to the service provided. See id. at 23. The fee-for-service arrangement was an invitation for physicians or health care providers to prescribe inordinate amounts of care, regardless of cost. See id.


32. Gonzalez, supra note 28, at 723 n.49.

33. See Walsh, supra note 31, at 213 n.31.
decrease their exposure to medical malpractice lawsuits. Finally, the rising costs could be most attributable to the corporatization of health care and the struggle for pharmacies, doctors, hospitals, pharmaceutical manufacturers, and health insurance companies to earn profits simultaneously. Despite these rising costs, other countries provide their citizens with better health care at lower costs.

In response to increasing costs and decreasing care, former President William Jefferson Clinton sought to reform health care by creating a system that would keep the cost of health care down while providing for care for "the entire population." Clinton criticized the health care system in the United States and saw shame in the fact "that 'infants die at rates that exceed countries blessed with far fewer resources'" and that "insurance companies routinely deny coverage to consumers with pre-existing conditions." The reform sought by Clinton ultimately failed.

The demise of the proposed health care reform ultimately led to the expansion of managed care plans that promised to provide health care at a reduced cost. A cost-containment mechanism was needed to put the cap on rising health care costs. MCOs came to the rescue, promising to lower health care costs by managing health care and eliminating unnecessary medical treatment. This promise of greater care at lower costs caught on quickly, making MCOs a popular choice among those in search of a quality health insurance plan. By the year 1995, just months after the failure of then President Clinton's proposed reform, seventy-three million people were covered by MCOs.

34. See id. at 214 n.31.
35. See id. at 359. In the ten year period spanning 1960 to 1970, hospital costs have risen 170 percent while doctors' fees have risen sixty percent. See Edward M. Kennedy, In Critical Condition: The Crisis in America's Health Care 54 (1972).
36. See Andrews, supra note 18, at 37 (citing a 1987 study which found that American doctors earn 5.4 times the salary of the average worker as opposed to the United Kingdom whose doctors earn only 2.4 times the average worker); Kennedy, supra note 35, at 220 (stating that the "United States pays more per capita for health care than any other industrialized nation in the world, but it gets less health care"). For example, the life expectancy for men and women in the United States ranks globally seventeenth and sixteenth, respectively. See Andrews, supra note 18.
37. See Birenbaum, supra note 28, at ix. Andrews, supra note 18, at 50.
38. Andrews, supra note 18, at 50.
39. See Birenbaum, supra note 28, at ix.
40. See id.
41. See Walsh, supra note 31, at 238.
42. See Thomas Maier, Managed Care and Doctors: The Broken Promise/HMOs and the Critical Lists/Managed Care Promises Only the Best, but Dozens of Their Doctors Have Troubled Past, Newsday, Nov. 14, 1999, at A4 (reporting that managed care promised "to lower health care costs while raising quality.").
43. See Walsh, supra note 31, at 238 n.244.
five percent of employees in the United States who were insured were part of a managed care organization. This was up dramatically from fifty percent participation in managed care in the year 1993.

We have seen the fuel for the rise in the prevalence of managed care plans, but not yet examined is the question of what exactly is managed care. Managed care may be defined as

any health care arrangement in which, for a pre-set fee (i.e., the premium), a company sells a defined package of benefits to a purchaser, with services furnished to enrolled members through a network of participating providers who operate under written contractual or employment agreements, and whose selection and authority to furnish covered benefits is controlled by the managed care company.

Managed care differs from traditional health insurance in a number of regards. Under traditional indemnity insurance, the insurance company contracts to reimburse the insured for the amount spent on health care. There is no agreement between physicians/providers ("Providers") and the insurance company; the patient chooses his Provider, the Provider bills the patient, and the patient subsequently submits the bill to the insurance company for indemnification. Under a traditional service benefit plan, Providers have contracts that dictate their rights and duties as well as the fees that they can charge. These types of insurance plans, similar to the one previously mentioned and contrary to the managed care model, merely sell coverage and not care. The capitalized plan model further sets forth a contract directly between the Provider and managed care organization in which the physician is paid a pre-set fee and in turn promises to provide care for all patients enrolled in the managed care plan.

44. See BIRENBAUM, supra note 28, at x.
45. See id. (referring to a national survey of approximately 2000 employers).
47. For purposes of this Note, Managed Care Organization ("MCO") will also include Health Maintenance Organizations, Preferred Provider Organizations, and all other structures of insurers prevalent in the marketplace today.
48. See ROSENBLATT ET AL., supra note 46, at 553.
49. When using the term Provider, this Note refers to physicians, hospitals, pharmacies, laboratories, and other health care providers who may provide services for the insured patient.
50. See ROSENBLATT ET AL., supra note 46, at 553.
51. See id.
52. See id.
53. See id.
Traditionally, medical care in the United States has been provided on a "fee-for-service" basis—a physician charges for a service, billing either the patient or the insurer. Under [the Managed Care] system, the physician balances the financial incentive to provide more services against the professional obligation to the patient to exercise reasonable medical care and judgment.  

Networks of Providers are characteristic of MCOs. The network is the term given to the group of Providers who choose to enroll with an MCO and provide care for the organizations’ enrolled patients. These Providers, who are under contract with the MCO, then provide care for those insured by it. The Providers are also subject to the control of the MCO in the tests and treatment they may offer. Physicians are "encouraged to see [their] patients with as little frequency as possible, to limit testing, and to make as few referrals to specialists" as possible. Patients are conversely told by the MCO that they are permitted to see those physicians who participate in the plan as often as they like. The physicians are told by the MCO to limit unnecessary visits by patients. The MCO is essentially trying to assure their enrollees that they will receive as much quality care as necessary while requiring the Providers to reduce costs and limit care. The bottom line is the bottom line of the Insurance company’s balance sheet.

Managed care gained its popularity by promising to lower the cost of health care. The system acts as a cost containment mechanism aimed at negating the drastic rise in health care costs. The key to managed-
care cost control is preventative medicine—that is discovering or preventing a problem through immunizations, medications or low-cost diagnostic tests, before the problem becomes a high-cost medical problem. Examples of this include inoculations to prevent infectious disease and prenatal examinations to prevent expensive premature births or other gestational problems.

III. THE PREVENTATIVE MEDICINE—CURATIVE MEDICINE NON-DISTINCTION

While MCOs promise care at a reduced cost by way of preventative medicine, many treatments or tests are not covered. MCOs have restrictions and exclusions that at the end of this section will be identified as preventative medicine. The truth of the matter is that the practice of medicine, almost the entire practice of medicine, can be classified as preventative medicine.

A number of examples will help to illustrate this proposition. Many children suffer from otitis media, or ear infections, as many mothers know it. One of the more heavily prescribed drugs for otitis media is Zithromax (azithromycin). Another popular remedy for the pain associated with otitis media is to insert a few drops of warm olive oil into the infected ear. While this may appear to be curative, it is also preventative—the olive oil will prevent further pain and while Zithromax may treat the underlying infection, it is also preventing progression of the infection, possibly from spreading to an uninfected body part, or even causing deafness.

66. See ANDREWS, supra note 18, at 30 (stating that part of the cost cutting campaign was “saturation of care at early phases of typical problems”).
67. See id.
68. See id. at 31.
69. See Marilyn Chase, Drug-resistant Bacteria are Bugging Little Ears, FORT WORTH STAR-TELEGRAM, April 18, 1999, at 13 (blaming otitis media for twenty-six million doctor visits per year).
70. See id. (indicating Zithromax as a common treatment for otitis media).
71. See Martha Schindler, Now Ear This, VEGETARIAN TIMES, Sept. 1998, at 58 (indicating olive oil as relief for pain associated with otitis media).
72. See id. Most pediatricians will put a child with an ear infection on antibiotics immediately without checking to see if the infection is bacterial (only half are). See id. Antibiotics have a tendency to build up bacteria’s resistance and lead to recurrent and chronic infections. See id. The alternative holistic remedies are more effective, readily available and cheaper than antibiotics. See id.; see also Susan H. Thompson, Why am I Deaf?, TAMPA TRIB., Aug. 19, 2001, at 8 (indicating that otitis media is one of the most common causes of loss of hearing in children).
Another common ailment is the flu, where body temperatures can reach in excess of 103 degrees Fahrenheit.\textsuperscript{73} Ibuprofen is often prescribed to reduce the fever.\textsuperscript{74} While it may seem that the medication was treating the fever, it was also preventing the condition from getting worse; when a fever is not lowered, it may continue to rise, ultimately to 106 degrees, possibly leading to death.\textsuperscript{75}

Internal bleeding may occur when an organ, such as the spleen, is ruptured.\textsuperscript{76} Physicians will operate to repair the damaged organ.\textsuperscript{77} While this may be deemed curative, it also prevents further bleeding, which if left untreated, could eventually result in death.\textsuperscript{78}

Hypertension is a fancy way of telling someone that they have high blood pressure.\textsuperscript{79} Physicians will often prescribe an ACE-inhibitor to control the blood pressure as well as modifying diet by decreasing sodium intake.\textsuperscript{80} While this may seem to be curative, it also prevents hypertension progressing to the point of heart attack.\textsuperscript{81}

These examples illustrate that when we look at medicine in a way that examines the outcome had treatment not been initiated, it becomes difficult to distinguish between curative and preventative medicine. Managed care relies on the preventative medicine model to achieve decreased costs,\textsuperscript{82} but when the distinction between preventative medicine and curative medicine becomes difficult to establish, a new standard is necessary. This Note now argues that the standard for whether or not a particular treatment should be covered by a managed care plan should be the reasonableness standard.

\textsuperscript{73} See Bernice McShane, \textit{Help Fever be a Friend, Not Foe}, SUNDAY OKLAHOMAN, Jan. 29, 1995, at 3 (indicating that the flu can cause body temperature to rise to 103 degrees).
\textsuperscript{74} See Nancy H. Montville & Mary A. White, Diagnosis and Pharmacological Management of Acute Otitis Media, PEDIATRIC NURSING, Sept. - Oct. 1998, at 423 (indicating Ibuprofen as an antipyretic).
\textsuperscript{75} See Joseph B. Verrengia, \textit{Heat Deaths Are All too Common}, CHATTANOOGA TIMES, Aug. 2, 2001 at D2 (indicating that death occurs at body temperatures above 106 degrees).
\textsuperscript{76} See, e.g., Fosberg Takes Extended Leave, N.Y. TIMES, Sept. 17, 2001, at 19 (discussing how doctors had to operate on a hockey player's spleen, after it ruptured, in order to stop the internal bleeding).
\textsuperscript{77} See id.
\textsuperscript{78} See Jules Crittenden & Dave Wedge, Man Charged For Alleged Punch That Killed Pal, BOSTON HERALD, Apr. 14, 2002, at 14 (noting that a man died as a result of internal bleeding after being punched in the stomach).
\textsuperscript{79} See Morris J. Brown, Blood-Pressure-Lowering Treatment, LANCET, Mar. 3, 2001, at 715 (discussing how when treating hypertension, the goal is to reduce blood pressure).
\textsuperscript{80} See id.; see also Joseph Graedon & Teresa Graedon, \textit{The People's Pharmacy: Undoing the Effects of Laxative Abuse}, NEWSDAY, Apr. 2, 2002, at D4 (noting that a diet low in sodium might help lower blood pressure).
\textsuperscript{81} See Brown, supra note 79, at 717.
\textsuperscript{82} See BIRENBAUM, supra note 28, at 17.
IV. THE REASONABLENESS STANDARD

Maybe more than any other industry, managed care administrators are forced to make decisions that may ultimately cause harm to a great number of individuals who rely on their service. The administrator of a managed care plan is often forced to decide between insuring an expensive state of the art treatment with potential medical benefits or refusing such coverage and subjecting patients to older, less expensive, less beneficial treatments. It denies these more expensive treatments on the ground that “some treatment or service is not medically necessary.” The ultimate decision comes down to dollars and cents for the managed care administrator, but sometimes on the patient level, the decision is the difference between life and death. The MCOs may decide to reject a new therapy on the grounds that the benefit over the existing treatment is minimal while the excess costs are great. This, however, would hardly console the patient whose life could have been saved given the minimal additional benefit.

In running any successful business, it is necessary to take into account many costs and benefits. Thus, as a business, it is understandable that administrators often take into account the costs and benefits of treatments in making the ultimate decision as to whether to insure such treatment. However, this Note argues that MCO decisions should be judged by the reasonableness standard established over fifty years ago.

In the year 1947, the Honorable Learned Hand authored the landmark opinion in United States v. Carroll Towing Co., in which it was established that costs are to be considered in determining whether a party is negligent. The formula in determining a party’s liability for negligent conduct as discussed in Carroll Towing Co. is that when the probability of harm multiplied by the gravity of harm is greater than the “burden of adequate precautions,” a party’s conduct is negligent. If the “burden of adequate precautions” exceeds the gravity of probable harm

83. See WONG, supra note 63, at 14-15.
84. Lawrence H. Mirel, We Call it Insurance, But That’s Not Healthy, WASH. POST, Aug. 26, 2001, at B2 (arguing that “[t]he current system for paying the costs of health care is seriously flawed”).
85. See WONG, supra note 63, at 14-15.
86. See generally Fergal Byrne, Starting on the Hard Road to a Winning Formula, FIN. TIMES, Mar. 30, 2000, at 15 (discussing how entrepreneurs need to consider cost and benefits when starting up a business).
87. 159 F.2d 169 (2d Cir. 1947).
88. See id. at 173.
89. See id.
to occur, the injured party is to sustain the harm without compensation. The formula for negligent conduct is often cited as $B < P^*L$ ("Hand Formula"). What *Carroll Towing Co.* teaches us is that there will be situations in which a party must make a decision in which harm to others will result; these decisions are ultimately justified if the cost of preventing the harm is greater than a function of the probability of the harm actually occurring and the amount of harm that occurs. However, if the harm could be prevented at a cost that is lower than probable damage that will be sustained, the party causing the harm will be deemed to be negligent and will be responsible for making the harmed party whole.

The facts in *Carroll Towing Co.* involved an unattended barge that ultimately caused damage to other barges in the nearby North River. The Hand Formula used in *Carroll Towing Co.* has not been limited to harm caused in barge accidents. The cost-benefit analysis developed by Learned Hand has been applied to cases involving defective oil tankers, defective design on cigarette cartons that fail to warn smokers of the risks of smoking, banking law and negotiable instruments, copyright infringement, contaminated blood plasma, and endless other factual scenarios.

The reason that the reasonableness standard has not yet been applied to claims of harm caused by denied medical benefits is that such claims are preempted by ERISA. The "Patients' Bill of Rights" will ultimately be passed through Congress giving patients the power to bring tort and contract claims against MCOs. Once MCOs are


91. See *Carroll Towing Co.*, 159 F.2d at 173.
92. See *id.*
93. See *id.*
94. See *id.* at 170.
100. See CURRAN ET AL., *HEALTH CARE LAW AND ETHICS* 529-31 (5th ed. 1998). For greater detail, see discussion infra Part VI.
101. See *Curing the Patients' Bill of Rights*, N.Y. TIMES, Sept. 4, 2001, at A22 (stating that a "patients' rights bill is headed for a House-Senate conference committee" at which point Congress
vulnerable to suit for negligent decisions to deny treatment, those
decisions should be judged by the reasonableness standard.

In applying this standard, a court is to use the Hand Formula to
determine whether the cost of paying for a certain procedure or
treatment is greater than the product of the magnitude of the harm that
would result from denying the treatment and the probability that such
harm would occur. Applying this formula, an MCO administrator could
deny treatment only if the cost of rendering such treatment is greater
than the harm that would be caused to the patient by failing to render
treatment. This would be considered “good harm” because the social
good exceeds the harm to the individual.102 As an illustration, an MCO
would be justified in denying laser eye surgery to its enrollees because
the “cost of avoidance” would simply be to have its enrollees wear
glasses or contact lenses and the cost of laser eye surgery often costs
between $1500 and $2000 per eye.103 On the contrary, the MCO would
be liable for a decision in which a simple glaucoma test was denied since
the cost of such a procedure is minimal and the harm that might result
includes the loss of vision.104 Of course, these are simplistic examples,
and do not include a detailed examination of side effects, likelihood of
side effects, and the cost of the side effects.

V. HOW ERISA BARS PLAINTIFFS FROM SUING THEIR
HEALTH INSURERS

The judicial system of the United States acts as a forum for harmed
individuals to recover damages from those who have committed the
harm.105 When a physician or hospital causes that harm, state law
provides the plaintiff an opportunity to sue for medical malpractice.106
However, with the evolution of the health care system in America, the

claim for intentional infliction of emotional distress because the social good derived from
defendant’s conduct far outweighed the harm).
103. See Milt Freudenheim, Just What is it that Carl Icahn Sees in Visx? Eye Laser Company
104. See Feature Report; Preserving Your Sight, CONSUMER REPORTS ON HEALTH, Feb. 2002.
at 1 (noting that if cataracts goes untreated it could cause loss of vision).
105. While this may be the case, “[t]he meagerness of the ERISA remedy in comparison to the
remedies available in a negligence suit provides HMOs with an incentive to deny care.” Federal
Preemption of State Law – ERISA – Fifth Circuit Upholds State Statute Allowing HMOs To Be Sued
physician or hospital is not always the party making the medical decisions.\textsuperscript{107} This is where the legal void created by ERISA becomes troublesome.\textsuperscript{103} ERISA, originally enacted by Congress as an effort to protect the retirement benefits of workers, was drafted so broadly as to also encompass all benefit plans, including health insurance, provided by employers.\textsuperscript{109} As such, federal law will preempt any claim that relates to the health benefit plan, and the plaintiff seeking to recover must file their complaint in the federal courts.\textsuperscript{110} Herein lies the problem—a plaintiff seeking to recover from a health benefit plan for harm resulting from a denial of treatment must allege that such lack of treatment was negligent;\textsuperscript{111} a plaintiff seeking to assert such federal tort law will discover that no such law exists.

In order for a claim to be preempted by ERISA, the state law must "relate to" the employee benefit plan.\textsuperscript{112} "Courts have interpreted ERISA's preemption clause broadly" in an effort to comply with Congress' intent to "make ERISA 'an area of exclusive federal concern.'"\textsuperscript{113} Despite the broad interpretation given to ERISA, the "savings clause," 29 U.S.C. § 1144(b)(2)(A), provides that "[e]xcept as provided in subparagraph (B), nothing in this subchapter shall be construed to exempt or relieve any person from any law of any State.

\textsuperscript{107} See Walsh, supra note 31, at 209.
\textsuperscript{108} See generally CURRAN, supra note 99.
\textsuperscript{109} See Larry J. Pittman, ERISA's Preemption Clause and the Health Care Industry: An Abdication of Judicial Law-Creating Authority, 46 FLA. L. REV. 355, 357-58 (1994) (stating that Congress enacted ERISA in response to "certain abuses that were occurring in employee pension plans"). Specifically, in the early 1970s many pension plans were insufficiently funded and employers used creative tactics to avoid compensating their long-time employees through their pension plans. See id. at 358.
\textsuperscript{110} See id. at 387.
\textsuperscript{111} See id. at 366-67.
\textsuperscript{112} See 29 U.S.C.S. § 1144(a) (1995). Specifically, the statute states "[e]xcept as provided in subsection (b) of this section, the provisions of this [title and title IV] shall supersede any and all State laws insofar as they may now or hereafter relate to any employee benefit plan described in section 1003(a) of this title and not exempt under section 1003(b) of this title." Id. In order to prevent states from disguising regulation of employee benefits as mere regulation of insurance, Congress drafted the ERISA "deemer clause" to state as follows:

Neither an employee benefit plan . . . nor any trust established under such a plan, shall be deemed to be an insurance company or other insurer, bank, trust company, or investment company or to be engaged in the business of insurance or banking for purposes of any law of any State purporting to regulate insurance companies, insurance contracts, banks, trust companies, or investment companies.

29 U.S.C. § 1144(b)(2)(B) (1995). This language seems to broadly preempt any health insurer. In order to remedy this, the "savings clause" of ERISA removes any insurance plan that is not provided by an employer as an employee benefit. See 29 U.S.C. § 1144(b)(2)(A); see also Bill Gray Enters. Inc., v. Gourley, 248 F.3d 206, 212 (3d Cir. 2001).

\textsuperscript{113} Gourley, 248 F.3d at 212 (citing FMC Corp. v. Holliday, 498 U.S. 52, 58 (1990)).
which regulates insurance, banking, or securities.\footnote{29 U.S.C. § 1144(b)(2)(A) (1995). “While ERISA broadly preempts state regulations of employee benefit plans, it does not preempt state laws governing insurance.” Gourley, 248 F.3d at 212.} This language removes all non-employer provided health benefits from ERISA preemption.\footnote{See Medical Mut. v. DeSoto, 245 F.3d 561, 573 (6th Cir. 2001) (stating that “[u]nder Supreme Court precedent, a self-funded plan may not be deemed an insurance company and therefore will be exempt from saved state laws”). The court went on to note that “[a]n insured plan . . . is deemed an insurance company and therefore is subject to the requirements of saved state laws.” Id. Thus, if a “benefit plan is an insured plan,” it will not be “protected from state law by ERISA’s ‘deemer clause.’” Id.}

Due to this unintended consequence of ERISA, Congress’ intent to protect employees’ benefits has become frustrated because ERISA ultimately acts as a bar to negligence suits against MCOs.\footnote{See Pittman, supra note 109, at 361.} A suit that has been brought in state court by a plaintiff claiming negligence against their MCO will ultimately be removed to federal court upon the MCO’s motion.\footnote{See Pryzbowski v. U.S. Healthcare, Inc., 245 F.3d 266, 270-75 (3d Cir. 2001) (outlining the procedure for removal to federal court and the considerations that a court must make in determining whether the claim relates to employee benefits).} This limits the plaintiff to the equitable remedies provided for under ERISA.\footnote{See Jeffrey A. Brauch, The Federal Common Law of ERISA, 21 Harv. J.L. & Pub. Pol’y 541, 547-50 (1998) (stating that Congress gave the judiciary the authority to create federal common law in claims brought in federal court under ERISA); see also Federal Preemption of State Law—ERISA—Fifth Circuit Upholds State Statute Allowing HMOs to be Sued for Doctors’ Negligence, supra note 105, at 1406. For an overview of the remedies available to plaintiffs and how each federal circuit interprets ERISA claims, see generally Brauch, supra.} Specifically, plaintiffs will usually be limited to reimbursement for actual plan benefits; in other words, the plaintiff may recover the monetary value of the procedure that was denied by the MCO, but may not be awarded monetary damages for the actual harm that resulted from the refusal of insurance coverage for that procedure.\footnote{See Richard Rouco, Available Remedies Under ERISA Section 502(a), 45 Ala. L. Rev. 631, 643 (1994) (stating that damages are limited to “actual plan benefits.”). For an illustration of the limitation of remedies available under ERISA, see Mertens v. Hewitt Associates, 948 F.2d 607, 612 (9th Cir. 1991) (holding that monetary damages are not available under ERISA as a form of equitable relief).} This will all soon change as the ERISA bar to state law tort claims against MCOs will be sidestepped by the Patients’ Bill of Rights.
VI. THE FEDERAL AND STATE RESPONSE TO ERISA’S BAR ON CLAIMS

A. Federal Response—The Proposed Patients’ Bill of Rights

The greatest weapon that plaintiffs may have against a decision by an MCO to deny treatment has been stuck in Congress in Conference Committee for some time now. The Patients’ Bill of Rights, once passed into law will allow plaintiffs to sue MCOs for both a lack of quality and quantity of care. The bill has been stuck in Conference Committee due to the inability of the Senate and House of Representatives to agree on the amount of damages that could be recovered by plaintiffs. Ironically enough, due to recent efforts by the judiciary to limit ERISA’s “relates to” language, and thereby allow more and more lawsuits to escape ERISA preemption, the Patients’ Bill of Rights stands to benefit MCOs more than the patients it is intended to protect.

B. Judicial Response—Efforts to Limit the “Relate To” Language of ERISA Allow More Claims to Be Brought in State Court

Realizing the legal void left by ERISA, and the inability of the House of Representatives and the Senate to come to an agreement on a definitive Patients’ Bill of Rights, the federal courts have made efforts to limit the “relates to” language of ERISA so as to allow more claims to escape the pitfall of preemption.

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120. See George M. Kraw, Patient’s Bill; Opportunities Abound for Insurers, FULTON COUNTY DAILY REP., Aug. 14, 2001. Note that patients are preempted if they sue their MCOs for a lack of quantity of care, but many state courts are now hearing claims relating to the quality of care provided by the MCO. See In re U.S. Healthcare, Inc., 193 F.3d 151, 161 (3d Cir. 1999) (holding in regard to complete preemption of plaintiff’s quality of care claim “[n]or could we find any basis in the legislative history [of ERISA] for concluding that quality claims, as opposed to quantity ones, would be completely preempted”).

121. See Kraw, supra note 120.

122. See id. The House of Representatives has drafted a bill that limits both compensatory and punitive damages at 1.5 million dollars. See id. The Senate version places the recovery cap at five million dollars. See id.

123. See id. “[T]he plaintiff bar was finally figuring out how to get around ERISA,” but the new “legislation blocks the growth of state court liability theories that were opening a back door to liability claims against insurers and HMOs.” Id. Further, where in state court, there is no limit on the amount of damages that may be recovered, the new federal law would limit those damages to some degree. See id.

One of the first attempts at limiting the "relate to" language of ERISA can be seen in the case of New York State Conference of Blue Cross & Blue Shield Plans v. Travelers Insurance Co., where the court realized that "[i]f 'relate to' were taken to extend to the furthest stretch of its indeterminacy, then for all practical purposes pre-emption would never run its course."\(^\text{125}\)

The Fifth Circuit has taken the approach that a claim does not "relate to" an ERISA plan if it applies neutrally to ERISA plans and other types of plans.\(^\text{126}\) This gives a state flexibility in exercising its police power over the quality of health care. The Texas statute at issue in Corporate Health Insurance, Inc. v. Texas Department of Insurance enabled patients to seek an independent review of MCO decisions as well as holding MCOs vicariously liable for the medical malpractice of their physicians.\(^\text{127}\)

The Fifth Circuit gave even more flexibility to plaintiffs in their review of Texas' efforts to provide protection to their citizens against MCOs.\(^\text{128}\) Texas "codified an ordinary care standard for health care treatment decisions" and allowed its citizens to bring suit if such substandard care causes harm.\(^\text{129}\) A "health care treatment decision" is defined as "a determination made when medical services are actually provided by the health care plan and a decision which affects the quality of the diagnosis, care, or treatment provided to the plan's insureds or enrollees."\(^\text{130}\) The Fifth Circuit interpreted the liability provisions of the Texas statute as a claim for vicarious liability on the part of the MCO for the negligent care of the physician as opposed to the negligence on the part of the MCO per se.\(^\text{131}\) The court went on to state that it was not Congress' intent when drafting ERISA to supplant state regulation on the quality of medicine.\(^\text{132}\) This argument is strengthened when it is taken into consideration that Congress has never adopted a federal medical malpractice law. The Fifth Circuit essentially treated "health care

\(^{125}\) Id. at 655.

\(^{126}\) See Corp. Health Ins., Inc. v. Texas Dep't of Ins., 215 F.3d 526, 535 (5th Cir. 2000) (stating that "[a] law does not 'refer to' ERISA plans if it applies neutrally to ERISA plans and other types of plans").

\(^{127}\) See id. at 531 (discussing the three prongs of regulation authorized by Texas Senate Bill 386). Texas also provides a statutory cause of action against MCOs. See TEX. CIV. PRAC. & REM. CODE ANN. § 88.002 (Vernon 2002).

\(^{128}\) See TEX. CIV. PRAC. & REM. CODE ANN. § 88.002 (Vernon 2002) (providing a statutory cause of action against managed care entities).

\(^{129}\) See Corp. Health Ins., Inc., 215 F.3d at 531.

\(^{130}\) TEX. CIV. PRAC. & REM. CODE ANN. § 88.001 (Vernon 2002).

\(^{131}\) See Corporate Health Ins., Inc., 215 F.3d at 534.

\(^{132}\) See id. at 534-35.
treatment decisions” as negligent when the doctor, relying on standards set by the MCO, was unreasonable in light of ordinary care.\textsuperscript{133}

The Pennsylvania Supreme Court in \textit{Pappas v. Asbel}\textsuperscript{134} took a similar approach. There, it was decided “ERISA does not establish a cause of action for breach of fiduciary duty predicated upon a managed care organization’s ‘mixed eligibility’ decisions.”\textsuperscript{135} The court thereby allowed Pappas to bring his claim against his MCO for damages sustained from their decision to deny him a transfer to an unaffiliated hospital that had a spinal cord trauma unit.\textsuperscript{136}

This trend, initiated by the Fifth Circuit’s decision in \textit{Corporate Health Insurance, Inc. v. Texas Department of Insurance} was recently decided by the United States Supreme Court in \textit{Rush Prudential HMO, Inc. v. Moran}.\textsuperscript{137} In \textit{Rush}, the Supreme Court decision further limited the “relates to” language of ERISA.\textsuperscript{138} The court held that ERISA does not preempt plaintiffs from bringing claims against MCOs under the Illinois HMO Act.\textsuperscript{139} This holding further demonstrates the judicial trend to allow more claims to be brought under state law. Along these lines, the passage of the Patients’ Bill of Rights is likely to follow. This will require judges to adopt a standard for determining the outcomes of these claims.\textsuperscript{140} This Note now applies the proposed reasonableness standard to an MCO’s decision of whether or not to insure the prophylactic use of Cipro in patients unexposed to anthrax.

\textbf{VII. THE REASONABLENESS STANDARD APPLIED TO THE PROPHYLACTIC USE OF CIPRO IN UNINFECTED PATIENTS}

When a person has yet to be exposed to anthrax, it is unreasonable to expect a managed care plan to insure its enrollees for prophylactic Cipro treatment. The reason for this finding is that the overall costs of

\textsuperscript{133} See \textit{id.} at 535.

\textsuperscript{134} 768 A.2d 1089 (Pa. 2001).

\textsuperscript{135} \textit{id.} at 1097 (Saylor, J., dissenting) (referring to the majority’s holding).

\textsuperscript{136} See \textit{id.} at 1096. This is the type of case that has been historically preempted by ERISA. See Hull v. Fallon, 188 F.3d 939, 943 (8th Cir. 1999); Danca v. Private Health Care Sys., Inc., 185 F.3d 1, 7 (1st Cir. 1999); Jass v. Prudential Health Care Plan, Inc., 88 F.3d 1482, 1495 (7th Cir. 1996); Tolton v. Am. Biodyne, Inc., 48 F.3d 937, 943 (6th Cir. 1995); Kuhl v. Lincoln Nat’l Health Plan, 999 F.2d 298, 302 (8th Cir. 1993); Corcoran v. United Healthcare, Inc., 965 F.2d 1321, 1322 (5th Cir. 1992).

\textsuperscript{137} 122 S. Ct. 2151 (2002).

\textsuperscript{138} See \textit{generally id.}

\textsuperscript{139} See \textit{id.} at 2156.

\textsuperscript{140} See Pittman, \textit{supra} note 109, at 439-40.
insuring a supply of Cipro exceeds the potential harm that could result if
a non-exposed patient did not receive such treatment.\textsuperscript{141}

In order to illustrate this conclusion, a survey was administered
with questions concerning the recent anthrax outbreak and prophylaxis
with Cipro. The survey read as follows:

| 1) Please rate your overall knowledge of anthrax and the anthrax outbreak on a scale of 1 - 10 with 10 being the greatest knowledge |
| 2) Are you concerned about catching anthrax from an infected person that you may come into contact with?\textsuperscript{142} |
| 3) Do you know that Cipro is one of the treatments for anthrax? |
| 4) If you were to receive a free 60-day supply (standard dose of Cipro for anthrax treatment) of Cipro from your health insurance company, would you accept it?\textsuperscript{143} |

\begin{tabular}{|l|l|}
\hline
1 & 2 & 3 & 4 & 5 & 6 & 7 & 8 & 9 & 10 \\
\hline
\end{tabular}

\begin{tabular}{|l|l|}
\hline
\text{Yes/No} & \text{Yes/No} & \text{Yes/No} \\
\hline
\end{tabular}

\textsuperscript{141} See infra notes 142-53 and accompanying text.
\textsuperscript{142} This question was asked as a "check" to the first question. For example, those surveys that had '10' circled on the first question (claiming to have a lot of knowledge about anthrax) and then had "yes" as an answer to the second question (responding that they were concerned about catching anthrax from an infected person) were discarded as irrelevant. This is because anthrax is not contagious and an individual with great knowledge on the topic would not be concerned about catching anthrax. See Understanding Anthrax; Anthrax at a Glance, NEWSDAY, Nov. 6, 2001, at C7 [hereinafter Understanding Anthrax]. Thus, an answer of yes to the second question shows a lack of knowledge on the part of the survey-taker.

\textsuperscript{143} While this question may seem to imply an obvious answer, a detailed look into the calculation of health insurance premiums suggests a different answer. While an analysis of insurance premiums would encompass an entire scholarly article, and is not the purpose of this Note, a simplistic look would reveal that if massive numbers of individuals were to accept a sixty day supply of the expensive antibiotic, insurance premiums would be adjusted upward. See Kevin Lamb, 2001 Promises Higher Health Costs, DAYTON DAILY NEWS, Dec. 24, 2000, at 1A (comparing the rise in the use of health care services to the increase in health insurance premiums).

The results for this question show that human nature tends to respond positively to the word "free" without consideration of the consequences, and whether something is truly free of charge.
5) If your insurance company did not cover Cipro, would you pay $420 for a two month supply if it was not medically necessary (meaning that you were currently in good health)?

6) If your insurance company did not cover Cipro, would you pay a reduced rate of $120 for a two month supply if it was not medically necessary (again meaning that you were currently in good health)?

7) If you did receive a 60-day supply of Cipro, what would you do with it?

<table>
<thead>
<tr>
<th>Question</th>
<th>Answer</th>
</tr>
</thead>
<tbody>
<tr>
<td>5) If your insurance company did not cover Cipro, would you pay $420 for a two month supply if it was not medically necessary (meaning that you were currently in good health)?</td>
<td>Yes/No</td>
</tr>
<tr>
<td>6) If your insurance company did not cover Cipro, would you pay a reduced rate of $120 for a two month supply if it was not medically necessary (again meaning that you were currently in good health)?</td>
<td>Yes/No</td>
</tr>
<tr>
<td>7) If you did receive a 60-day supply of Cipro, what would you do with it?</td>
<td>Take it to prevent infection or Hold onto it “just in case”</td>
</tr>
</tbody>
</table>

The survey returned 186 responses from pharmacy patients, pharmacy technicians, nurses, physicians, hospital patients, lab technicians and elementary school teachers. The following are the results of the compiled data, which tend to support the argument that it would be unreasonable to expect MCOs to insure Cipro for prophylactic treatment when the patient is yet to be exposed to anthrax. Following the results of the survey will be a cost-benefit analysis as is required by the Carroll Towing decision.

The completed surveys were divided into three groups. Those who responded between one and three on the first question were regarded as individuals with little or no knowledge of the anthrax breakout and the disease in general. Those answering between four and seven on the first question were regarded as individuals with average knowledge of the anthrax breakout and the disease in general. Those answering between eight and ten on the first question, and responding “no” to the second question, were regarded as individuals with superior knowledge of the anthrax breakout and the disease in general. Those answering between eight to ten on the first question, and “yes” to the second question, were

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144. The cost of Cipro is approximately three dollars and fifty cents per tablet. See Rita Rubin, *Urinary Infection Treatment Often Isn’t First-Line Choice*, USA TODAY, Jan. 14, 2002, at D7 (calculating the 10 day cost of Cipro therapy at $70.98). A sixty day supply of the drug would therefore cost a patient approximately $420.

145. The calculation of approximately one dollar per tablet is based upon the theoretical price that the U.S. government was negotiating with both Bayer Pharmaceuticals and generic drug manufacturers. See Denise Gellene, *Anthrax Cases Reshape Drug Price Debate*, L.A. TIMES, Nov. 9, 2001, at C1 (stating that the United States is negotiating with Bayer Pharmaceuticals to purchase Cipro at ninety-five cents per tablet).

146. This survey is on file with the Author.
placed in the group regarded with little or no knowledge of the anthrax breakout and the disease in general.147

<table>
<thead>
<tr>
<th>Individuals with superior knowledge</th>
<th>Individuals with average knowledge</th>
<th>Individuals with inferior knowledge</th>
</tr>
</thead>
<tbody>
<tr>
<td>27.4% (51/186)</td>
<td>56.4% (105/186)</td>
<td>16.1% (30/186)</td>
</tr>
</tbody>
</table>

The following is a breakdown of the responses given by the individuals placed into the superior knowledge category:

<table>
<thead>
<tr>
<th>Question</th>
<th>Yes (%)</th>
<th>No (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Are you concerned about catching anthrax from an infected person that you may come into contact with?</td>
<td>0% (0/51)</td>
<td>100% (51/51)</td>
</tr>
<tr>
<td>Do you know that Cipro is one of the treatments for anthrax?</td>
<td>100% (51/51)</td>
<td>0% (0/51)</td>
</tr>
<tr>
<td>If you were to receive a free 60-day supply (standard dose of Cipro for anthrax treatment) of Cipro from your health insurance company, would you accept it?</td>
<td>82% (42/51)</td>
<td>18% (9/51)</td>
</tr>
</tbody>
</table>

147. Quite surprisingly, twenty-four, or 12.9% of all respondents fell into this category. I say surprisingly because of the extensive publicity that has been given to the anthrax breakout, and the repetitive assurance by President George W. Bush that anthrax is not contagious. See Michael Kranish, Fighting Terror National Concerns, BOSTON GLOBE, Nov. 4, 2001, at A1.

148. This result is quite surprising. I estimated that nearly every person would respond “yes” to this question simply because of the fact that the medication was supposed to be “free.” This may suggest that there are individuals who would not take advantage of insurance coverage when not necessary.
<table>
<thead>
<tr>
<th>Question</th>
<th>Yes Percentage</th>
<th>No Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>If your insurance company did not cover Cipro, would you pay $420 for a two month supply if \textit{it was not medically necessary} (meaning that you were currently in good health)?</td>
<td>3.9% (2/51)</td>
<td>96.1% (49/51)</td>
</tr>
<tr>
<td>If your insurance company did not cover Cipro, would you pay a reduced rate of $120 for a two month supply if \textit{it was not medically necessary} (again meaning that you were currently in good health)?</td>
<td>33.3% (17/51)</td>
<td>66.7% (34/51)</td>
</tr>
<tr>
<td>If you did receive a 60-day supply of Cipro, what would you do with it?</td>
<td>Take it to prevent infection 0% (0/51)</td>
<td>Hold onto it &quot;just in case&quot; 100% (51/51)</td>
</tr>
</tbody>
</table>

In light of the results acquired from these individuals, this Note poses the following question: Is it reasonable to ask an MCO, whose goal is to reduce the rising cost of health care by cutting down on unnecessary treatment, to insure a treatment that the beneficiary does not intend to utilize, but merely intends to hold onto it "just in case?" It is disturbing that an individual would rely on their MCO to insure an

149. These two individuals were both of the group who would accept the free supply from their insurance company.

150. Of these individuals, six were of the group who would refuse the free supply from their insurance company. This was quite surprising in that these individuals would refuse a free supply from their insurance company but were also not willing to pay full price. The only explanation is that these individuals did not want to defraud their MCOs, and either money was an issue or they did not feel that there was enough of a danger to justify spending $420 for a precautionary medication.
unnecessary treatment that the beneficiary does not feel is important enough to their health to pay for by themselves.  

The following is a breakdown of the responses given by the individuals placed into the average knowledge category:

<table>
<thead>
<tr>
<th>Question</th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>Are you concerned about catching anthrax from an infected person that you may come into contact with?</td>
<td>21.9% (23/105)</td>
<td>79.1% (82/105)</td>
</tr>
<tr>
<td>Do you know that Cipro is one of the treatments for anthrax?</td>
<td>100% (105/105)</td>
<td>0% (0/105)</td>
</tr>
<tr>
<td>If you were to receive a free 60-day supply (standard dose of Cipro for anthrax treatment) of Cipro from your health insurance company, would you accept it?</td>
<td>69.5% (73/105)</td>
<td>30.5% (32/105)</td>
</tr>
<tr>
<td>If your insurance company did not cover Cipro, would you pay $420 for a two month supply if it was not medically necessary (meaning that you were currently in good health)?</td>
<td>21.9% (23/105)</td>
<td>78.1% (82/105)</td>
</tr>
</tbody>
</table>

151. This, of course, assumes that the respondent was able to afford the Cipro treatment.
If your insurance company did not cover Cipro, would you pay a reduced rate of $120 for a two month supply if it was not medically necessary (again meaning that you were currently in good health)?

<table>
<thead>
<tr>
<th>Response</th>
<th>Yes 46.7% (44/105)</th>
<th>No 53.3% (61/105)</th>
</tr>
</thead>
</table>

If you did receive a 60-day supply of Cipro, what would you do with it?

<table>
<thead>
<tr>
<th>Response</th>
<th>Take it to prevent infection 10.4% (11/105)</th>
<th>Hold onto it “just in case” 89.6% (94/105)</th>
</tr>
</thead>
</table>

The responses of the individuals placed into the group with little or no knowledge broke down as follows:

<table>
<thead>
<tr>
<th>Question</th>
<th>Yes 93.3% (28/30)</th>
<th>No 6.7% (2/30)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Are you concerned about catching anthrax from an infected person that you may come into contact with?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Do you know that Cipro is one of the treatments for anthrax?</td>
<td>Yes 100% (30/30)</td>
<td>No 0% (0/30)</td>
</tr>
</tbody>
</table>

152. The percentage of respondents willing to pay for the antibiotic, whether it be full price or the reduced price, increased with the decreased knowledge (33.3% for the group with superior knowledge vs. 46.7% for the group with moderate knowledge). This implies that those with greater knowledge understand that Cipro will be made available by the government and that stockpiling the drug is not necessary.

153. The implications of this answer will be discussed in the cost-benefit analysis as well as in the discussion of what the physician and pharmacist can do to carry out the goals of the managed care company. Briefly, this answer shows that these individuals lack the proper understanding of the medication and the costs of taking the medication without being exposed to anthrax.

154. Once again, the great majority of individuals who would accept a supply of Cipro from their MCOs do not believe that the medication is necessary and would simply hold it “just in case.”
If you were to receive a free 60-day supply (standard dose of Cipro for anthrax treatment) of Cipro from your health insurance company, would you accept it?  

| Yes 100% (30/30) | No 0% (0/30) |

If your insurance company did not cover Cipro, would you pay $420 for a two month supply if it was not medically necessary (meaning that you were currently in good health)?  

| Yes 16.7% (5/30) | No 83.3% (25/30) |

If your insurance company did not cover Cipro, would you pay a reduced rate of $120 for a two month supply if it was not medically necessary (again meaning that you were currently in good health)?  

| Yes 53.3% (16/30) | No 46.7% (14/30) |

If you did receive a 60-day supply of Cipro, what would you do with it?  

| Take it to prevent infection 36.7% (11/30) | Hold onto it “just in case” 63.3% (19/30) |

The results of the survey illustrate two important points to be considered in answering the question of whether it is reasonable to expect an MCO to provide insurance coverage for prophylactic Cipro therapy when the insured is yet to be exposed to anthrax. The first point is that it would be unreasonable to expect the MCO, whose goal is to reduce the cost of health care, to insure a treatment which the patient does not intend to use and does not necessarily feel is necessary to insure...
Secondly, those individuals who answered that they would take Cipro in good health to prevent infection show a complete lack of knowledge; the cost of informing these individuals about anthrax infection is far less than the cost of paying for a two month course of Cipro, and is thus the reasonable alternative.\footnote{156}

A cost-benefit analysis of the prophylactic administration of Cipro for persons not exposed to anthrax reaches a similar conclusion. This Note first examines the benefits of taking Cipro for the prophylaxis of anthrax infection when the individual has not yet been exposed.

Only a few benefits are conceivable to this use of Cipro.\footnote{157} Nearly all of the respondents to the survey, whether they received the Cipro for free or paid out of pocket, answered that they would hold onto it just in case. This suggests that the mere possession of the antibiotic would give them peace of mind. While this may not be easily quantified, any benefit obtained through peace of mind is minimal. The responses to the survey also suggest that people may fear supplies of the antibiotic may become scarce. Government officials have repeatedly assured the public that this will not happen and to their word, it has not happened.\footnote{158}

Upon an examination of the costs of allowing those not yet infected to obtain Cipro from their Managed Care plans, it becomes obvious that these costs far outweigh the benefits, justifying the refusal of benefits by the MCO for such use of the medication.

The first cost is the potential for the mutation of Anthrax bacteria into a resistant strain.\footnote{159} Further, the “more people who don’t have...
bacterial infections take antibiotics, the less effective the drugs are when treating real problems, including [tuberculosis], pneumonia, and bad colds." It is estimated that thousands of U.S. residents treated themselves with Cipro out of fear without reporting the use to the CDC. This increases the chances that these individuals would build a resistance to the drug. The costs and consequences of this are that the usefulness of Cipro decreases and for those "infected by newly resistant germs, it means they will feel worse, for a longer time, and will pay more to get well." This negative effect is not limited to Cipro—the entire family of powerful quinolones becomes less effective. "[D]rug-resistant bacteria are pushing medical costs higher while making people sicker and cures longer and more painful." This is in direct contrast to the ultimate end that Managed Care strives to achieve. The quantified increase in the cost of health care in the United States due to drug resistance is about thirty billion dollars per year. Ultimately, only powerful intravenous antibiotics will be able to combat these germs, meaning a trip to the local hospital. These costs alone outweigh the potential benefits of Cipro for prophylactic purposes in non-exposed patients, but there are other costs.

Another cost of Cipro is its actual monetary cost—which as already stated is approximately $420 for a two-month supply. Please note that this is an approximate retail cost, which is closer to what MCO would be paying, as opposed to the actual cost.

As an antibiotic, Cipro contains dangers as well as side effects. The first danger is the use of Cipro by children. Since Cipro has an affinity to bone and joints, the drug often deposits itself within the

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160. Lerner, supra note 159.
161. See Dworkin, supra note 159.
162. See id.
163. Id.
164. See id.
165. Id.
166. See id.
167. See id. One of the most frequently encountered and dangerous resistant germs are those resistant to penicillin type antibiotics. See id. The reason for its frequency is because of fifty years of widespread penicillin use. See id. Cipro is often used as a second line of attack, and with the prophylactic use of Cipro for anthrax prevention, that may soon be lost as well. See id.
168. See supra note 142 and accompanying text.
169. See Dworkin, supra note 159; Reed Fujii, Demand for Cipro Not High in S.J., Pharmacists Say, RECORD (Cal.), Oct. 19, 2001, at F1 (explaining that Cipro can cause a number of side effects).
bone.\textsuperscript{170} In children less than eighteen years of age, Cipro can "produce erosions of cartilage of weight-bearing joints and other signs of arthropathy."\textsuperscript{171} Further dangers include dangerous interactions with other pharmaceuticals. The most serious of these is the combination of Cipro with theophylline, which can lead to cardiac arrest, seizure, respiratory failure and death.\textsuperscript{172} Further, antibiotics often produce unpleasant side effects. While over one hundred side effects are listed for Cipro, the most common (or in some cases most severe since cost is determined by probability times degree of harm) are: nausea (5.2%), diarrhea (2.3%), abdominal pain/discomfort (1.7%), headache (1.2%), cardiopulmonary arrest (<1%), and renal failure (<1%).\textsuperscript{173} In order to do a complete cost-benefit analysis, it would be necessary to multiply the probability of occurrence times the degree of harm to establish costs.\textsuperscript{174} Since pain and discomfort are subjective, quantifying them would be nearly impossible. For example, 2.3 out of every one hundred individuals develop diarrhea; the cost of diarrhea could be determined by measuring the amount of discomfort and the cost of treatment—for example, a few doses of Imodium. Such a detailed cost-benefit analysis is not necessary for purposes of concluding that Cipro prophylaxis in individuals not exposed to anthrax bacteria is not necessary. All that is necessary to ask is whether the minimal value of peace of mind and the risk of Cipro supplies running short exceed the value of developing dangerous resistant bacteria, the cost of potential bone malformation in children, and the discomfort of the side effects of Cipro plus $420 in actual cost.

If you have not yet determined that the cost of Cipro use in unexposed individuals far outweighs the benefits of such use, consider that Anthrax infection can be prevented by administering Cipro up to seven to ten days after exposure.\textsuperscript{175} Further corroborating the conclusion of this Note is the fact that there are adequate supplies of Cipro so as to

\textsuperscript{170} See id.; Fujii, supra note 169 (reporting that Cipro “has been linked to a degenerative joint disease that could attack those whose bones and sinews are still growing”).

\textsuperscript{171} Reprint of Cipro Tablet/Suspension Label at 12, available at www.fda.gov/ohrms/dockets/ac/00/backgd/5662b1a04.pdf (dated Aug. 29, 2000).

\textsuperscript{172} See id. at 14. Theophylline is a common medication used in the treatment of asthma. See Drug Information Center: Asthma, available at http://www.lungusa.org/asthma/ascastnedgr.html#preventive (last visited Jan. 4, 2002).

\textsuperscript{173} See id.

\textsuperscript{174} In a litigation setting, it is likely that expert witnesses would be required to present this data.

\textsuperscript{175} See Ivan Oransky, Antibiotic Overuse Can Silence Medicine’s Big Guns, USA TODAY, Nov. 15, 2001, at 15A (noting that originally Cipro was only to be taken for seven to ten days).
make stockpiling the drug unnecessary.\textsuperscript{176} As this Note establishes MCOs are not obligated to insure Cipro prophylaxis since such use would be unreasonable.\textsuperscript{177} This Note now discusses the health care providers’ role in decreasing the cost of health care.

\section*{VIII. The Providers’ Role}

In the Managed Care setting, the doctor agrees to provide care to the patient, but at the same time agrees with the MCO that he will only order such treatment as is medically necessary.\textsuperscript{178} As Cipro is an important antibiotic for the treatment of many bacterial infections,\textsuperscript{179} it would be unreasonable to ask MCOs to deny coverage for all Cipro regimens. The reasonable alternative would be to rely on the physician to refuse to prescribe Cipro outside the ordinary course of treatment. The physician’s role upon being asked for a Cipro prescription would be to educate the patient concerning the dangers of arbitrarily taking Cipro as well as informing the patient about Anthrax infection itself. The data compiled in the survey suggests that the less information an individual has regarding anthrax infection, the greater he or she fears contracting the disease from an infected person. With greater information, these individuals may understand that anthrax is not contagious, and stockpiling Cipro or, even worse, arbitrarily taking the drug for prophylactic purposes is simply not necessary when there has been no anthrax exposure. The cost of this education session might be to take a few minutes of the physician’s time each day (when patients ask for Cipro prescriptions) to educate patients. The benefit however, of avoiding unnecessary Cipro prophylaxis would make up for this cost. If time is an issue for the physician, the MCO could develop informational pamphlets to be administered to patients who ask for Cipro prescriptions.

The pharmacist, another provider in the Managed Care structure, can also play a role in preventing the widespread prophylactic use of Cipro. As the last line of defense between the patient and the medication, the pharmacist can refuse to either fill a two-month prescription for Cipro or actually fill the prescription but refuse to bill the MCO, thereby requiring the patient to pay cash. It is possible that MCOs will bill

\begin{footnotesize}
\begin{enumerate}
\item[176.] See Fujii, supra note 169.
\item[177.] See id.
\item[178.] See Mirel, supra note 84.
\item[179.] See Stolberg, supra note 13.
\end{enumerate}
\end{footnotesize}
pharmacies back for suspicious Cipro prescriptions.180 This gives pharmacists a justification for refusing to bill insurance carriers for such prescriptions. An alternative to this would be for insurance administrators to electronically refuse such Cipro treatments by automatically refusing any Cipro prescription with a regimen of thirty or sixty days.181

Ultimately, it becomes apparent that there is not much that the MCO can do without the help of other Providers. It is up to physicians and pharmacists to provide information to educate the patient. Further, the Provider must work to keep health care costs down by refusing to prescribe or administer any prescriptions for Cipro that are not medically necessary.

IX. CONCLUSION

Recent events have left the public unsettled and wondering from where the next harm will come. Recent fears center on unprecedented bioterrorism involving Anthrax.182 Individuals have looked to their health care professionals for Cipro, a treatment for Anthrax, in order to calm their fears.183 For those health care professionals, it is unreasonable for them to accommodate those patients. Further, the act of prescribing Cipro for patients not exposed to Anthrax bacteria violates the agreement the physician has with the MCO which obliges the physician to only render such care as is medically necessary. The reason such treatment is unnecessary is that the harm caused to society and the individual by such treatment far outweighs any benefits that it may have.

This reasonableness standard has been applied to many different areas in the past beginning with the case of Carroll Towing in which Learned Hand developed the formula for reasonableness as $B < P * L$. This standard has yet to be applied in cases where an MCO decision not to insure a specific treatment is at issue. The reason for this legal void is ERISA, which preempts such claims from being brought in state court. When brought in federal court, plaintiffs find themselves without any tort law precedent. Congress, realizing that this legal void gives patients no bargaining power with their MCO, and often leaves patients with no

180. Interview with Carol Martin, Supervisor, National Prescription Administrators, in East Hanover, N.J. (Dec. 12, 2001).
181. AdvancePCS has taken this approach by limiting Cipro prescriptions to twenty-eight pills or a fourteen day supply. Interview with Thomas Reidlinger, Supervisor, AdvancePCS, in Richardson, Tex. (Dec. 3, 2001).
182. See supra notes 8-11 and accompanying text.
183. See supra notes 12-13 and accompanying text.
recourse when an MCO denies treatment, has begun to consider a Patients' Bill of Rights. When adopted, the Patients' Bill of Rights will give patients the ability to bring tort and contract claims against their MCO. Some state courts have already begun to sidestep ERISA by allowing some borderline claims to be heard. When hearing such claims, the courts construing state statutes have applied a reasonableness standard. This is the standard that should be applied to all “health care treatment decisions.” In other words, an MCO would be justified in denying any treatment to a patient when the cost of such treatment is outweighed by the potential harms as measured by the Hand Formula. If the MCO denies treatment when the benefits of the treatment outweigh the cost, they will be liable for the resulting harm that arose from the decision to deny treatment. The Hand Formula for measuring reasonableness has been successfully applied to many industries in the past, and there is no reason to believe that it should not be applied to MCO decisions in the future.

Daniel L. Freidlin*

* This Note is the product of many life-altering decisions, not the least of which was turning my back on the well-respected profession of Pharmacy. For their endless support throughout this transitional period in my life, their guidance, and encouragement, this Note is dedicated to my parents, Boris and Mila Freidlin, without whom I would be unable to achieve success throughout my academic and professional endeavors. I would like to thank Dr. Joel Weintraub, J.D., who planted the seed which gave rise to this Note, and whose stream of insight helped it to grow into this finished product. My deepest gratitude to the Board of Editors and Staff of the Hofstra Law Review for their ongoing dedication to excellence, and their tireless efforts in preparing this Note for publication. One day Health Care in America may be more about health and less about dollars; until that day, I hope this Note has provided some insight into how the law can make Health Care a more efficient system.