

**TREATING THE HEALTH CARE CRISIS:
COMPLEMENTARY AND ALTERNATIVE MEDICINE FOR
PPACA**

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ABSTRACT

The Patient Protection and Affordable Care Act (PPACA) intends to take American health care in a new direction by focusing on preventive medicine and wellness-based treatment. But, in doing so, it does not adequately take into account the potential contribution of complementary and alternative medicine (CAM). CAM is already used by a large and growing number of individuals in the United States, although to date there is limited scientific evidence to support the efficacy of most CAM treatments. This article proposes statutory reforms to PPACA to encourage CAM research and development (R&D), and the use of demonstrably effective CAM treatments. A hybrid system of limited intellectual property protection and government prizes based on regulatory approval may be the best option for incentivizing R&D on CAM, along with increased funding for research through the National Institutes of Health. PPACA should require health insurance plans to reimburse for evidence-based CAM and empower an existing government agency (NCCAM) to regulate CAM standards and to recommend evidence-based CAM services. Together these policy and funding mechanisms should help reduce U.S. healthcare costs and improve quality of life.

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I: INTRODUCTION

American health care is in crisis. The United States has the least universal, most costly health care system in the developed world.¹ Moreover, when compared with other industrialized nations, American health care performs poorly in many respects. In a recent national survey, only eighteen percent of the public responded that the system works well.² The crisis is complex. The American health care system has increasingly relied on expensive, invasive treatments that may carry a high risk of adverse effects. While the system has generally been successful with acute conditions, it has been substantially less successful in treating chronic diseases and improving quality of life.

Recent health care reform under the Patient Protection and Affordable Care Act (PPACA) is designed to address problems with the mainstream medical model. Among other initiatives, PPACA emphasizes preventive and wellness-based approaches to care. This is expected to improve outcomes and lower health care costs. But PPACA does not go far enough. This article argues that reforms should include enhanced integration of evidence-based complementary and alternative medicine (CAM) into the U.S. health care system. CAM treatments have the potential to improve disease treatment outcomes and quality of life at a relatively low cost. Amendments to PPACA might establish new mechanisms for stimulating private sector CAM research and development, such as a market exclusivity regime and/or government prizes for FDA approval of a CAM product through a New Drug Application (NDA). While greater reliance on CAM is unlikely to be a panacea for the ills of the American health care system, it has meaningful potential to help.

Section II of this article provides background on the health care crisis. It presents evidence that American health care is overpriced and underperforming, and discusses some of the root causes. This section also provides a summary of the most important features of PPACA and its focus on prevention and wellness.

Section III discusses CAM, providing background on CAM use both domestically and internationally. It presents the potential benefits of CAM,

1. See generally Barbara Starfield, *Is US Health Really the Best in the World?* 284(4) JAMA 483 (2000).

2. See generally Robert J. Blendon et al., *The Public Versus The World Health Organization on Health System Performance*, 20(3) HEALTH AFFAIRS 10, 10 (2001).

along with some of the evidence supporting clinical efficacy and cost-effectiveness. This section also describes risks associated with the use of CAM, including problems with efficacy, safety, and appropriate use.

Finally, Section IV explains how the legislative mandate of PPACA justifies including CAM in health care reform. It analyzes intellectual property protection, regulation, research, and consumer protection as it relates to CAM in the United States. It argues for insurance reimbursement of evidence-based CAM treatments, increased government subsidies for research, and mechanisms to encourage private research and development.

No silver bullet solution exists to reform the American health care system. The system represents a very substantial part of American economic activity—increasingly so as the population ages. Potential legislative mandates affect a myriad of economic and social interests. Taking this complexity into account, more deeply integrating CAM through the approaches suggested in this article should be part of the long-term solution.

II: UNDERSTANDING THE PROBLEM

The American Health Care Crisis

The health care system in the United States faces very significant challenges. American health care is the most expensive in the world. In 2009, Americans spent \$2.5 trillion on health care, or \$8,086 per person, accounting for 17.6 percent of the gross domestic product (GDP).³ Spending is expected to increase at a much higher rate than in the past, and by 2020, health care spending is projected to consume twenty-one percent of the GDP.⁴

Not only is the American health care system the most expensive, it is also the least accessible of any health care system in a developed country.⁵ In 2008, the U.S. Census Bureau reported that 46.3 million people were uninsured (15.4 percent of the population) and an additional 25 million were underinsured.⁶ An estimated 18,000 adults die prematurely every

3. *NHE Fact Sheet*, CENTERS FOR MEDICARE & MEDICAID SERVICES, http://www.cms.gov/NationalHealthExpendData/25_NHE_Fact_Sheet.asp.

4. HealthCast 2020: Creating a Sustainable Future, *Pricewaterhouse Coopers' Health Research Institute*, http://download.pwc.com/ie/pubs/Healthcast_2020.pdf, at 4.

5. See Gerard F. Anderson et al., *Multinational Comparisons of Health Systems Data, 2002*, at http://www.commonwealthfund.org/~media/Files/Publications/Chartbook/2002/Oct/Multinational%20Comparisons%20of%20Health%20Systems%20Data%20%202002/anderson_multinatcomparisons2002_582%20pdf.pdf, at 4.

6. Elenora E. Connors and Lawrence O. Gostin, *Health Care Reform - A Historic Moment in US Social*

year from lack of insurance.⁷ The lack of health insurance can lead to financial insolvency.⁸ An estimated half of all bankruptcy filings in the U.S. involve medical expenses.⁹ A recent Kaiser survey found that more people are worried about their health care costs than about losing their jobs, paying their mortgages, losing money in the stock market, or being victims of a terrorist attack.¹⁰

With U.S. per capita spending on health care more than double the average of other industrialized nations, Americans should expect commensurate value and superior performance. However, recent studies of medical outcomes and mortality and morbidity statistics suggest that, despite its spending, the U.S. performs poorly when compared with other industrialized nations. In 2000, a World Health Organization (WHO) report stated that the health care system in the United States ranked 37th in the world.¹¹ According to the Organization for Economic Co-operation and Development (OECD), the United States ranks 22nd out of OECD countries in terms of life expectancy, despite spending the most on health care per capita as a percentage of GDP.¹² It ranks low as compared to almost all industrialized countries, with approximately six deaths per 1,000 live births as compared to 2.2 in the top three countries.¹³ According to the Institute of Medicine (IOM) Roundtable on Evidence-Based Medicine:

Health care in the United States currently underperforms on many dimensions. From the global perspective, with per capita

Policy, 303(24) JAMA 2521 (2010).

7. Timothy Stolfus Jost, *Our Broken Healthcare System and How to Fix It: An Essay on Health Law and Policy*, 41 WAKE FOREST L. REV. 537, 546 (2006).

8. Businesses are struggling to keep up with the increasing cost of health care. The cost of health care is among the top five issues facing small businesses today. Solving the Small Business Health Care Crisis: Lowering Costs and Covering the Uninsured: Before the Senate Committee on Small Business, 109th Cong. 1 (2005) (statement of William N. Lindsay, III, former Chair of the National Small Business Association (NSBA)). Even large businesses are finding it difficult to operate given the high cost of providing health care benefits. General Motors reported that it added \$1,500 to the price of every vehicle to provide health care insurance for its employees; it reportedly spent more than \$5.6 billion in 2005 on health coverage for 1.1 million people. Jeff Jacoby, *GM's healthcare dilemma*, BOSTON GLOBE (Jun. 16, 2005). The burden of high health care costs weakens the ability of the United States to compete globally and threatens to destabilize the economy. See Pricewaterhouse Coopers, *supra* note 4, at 12.

9. David U. Himmelstein et al., *Illness and Injury as Contributors to Bankruptcy*, 24 HEALTH AFFAIRS W5-63, W5-70 (2005).

10. *Kaiser Health Poll Report: Health Care Worries in Context With Other Worries*, KAISER FAMILY FOUNDATION (Mar./Apr. 2005), at www.kff.org/healthpollreport/apr_2005/security/1.cfm.

11. World Health Organization (WHO), *Health Systems: Improving Performance*, THE WORLD HEALTH REPORT 2000, <http://www.who.int/whr/2000/en/>, at 155.

12. Pricewaterhouse Coopers, *supra* note 4, at 14.

13. The World Factbook - Country Comparison: Infant Mortality Rate, CENTRAL INTELLIGENCE AGENCY (CIA), at <https://www.cia.gov/library/publications/the-world-factbook/rankorder/2091rank.html> (Last visited Jan. 28, 2012).

expenditures more than twenty percent higher than any other country in the world and more than twice the average expenditure for European countries, the nation ranks well below at least two dozen others on key health indices such as infant survival and life expectancy.¹⁴

Evidence also indicates that the United States performs poorly in terms of providing care equitably, safely, efficiently, timely, and in a patient-centered manner. Compared to patients in several other industrialized countries, patients in the United States suffered from the highest rate of medical error.¹⁵ A 2006 Institute of Medicine (IOM) report found that medication errors are surprisingly common and are costly to the nation.¹⁶ The IOM states that there are at least 1.5 million preventable adverse drug effects in the United States each year, and that the true number may be much higher. Another IOM study suggested that medical error is the country's eighth-largest cause of death.¹⁷ Beyond the suffering this causes to both patients and health care providers, a conservative estimate of the cost of medical error is \$3.5 billion for 2006.¹⁸

High levels of inappropriate care exacerbate the situation.¹⁹ A 2003 study found that patients in some areas of the country receive sixty percent more services—hospital days, specialty consultations, and medical procedures—than similar patients in other areas. Despite the variability in the amount of services provided, patients receiving more services had the same mortality rates, quality of care, access to care, and patient satisfaction.²⁰ One review article concluded “almost every study that has seriously looked for overuse has discovered it, and virtually every time at least double-digit overuse has been found. If one could extrapolate from the available literature, then perhaps one-fourth of hospital days, one-

14. The IOM Roundtable on Evidence-Based Medicine, *Learning Healthcare System Concepts v. 2008*, INSTITUTE OF MEDICINE (IOM), <http://www.iom.edu/~media/Files/Activity%20Files/Quality/IntegrativeMed/Health%20and%20Medical%20Economics--Applications%20to%20Integrative%20Medicine.pdf>, at 3.

15. *Health News, U.S. Patients Suffer More Medical Errors*, UPI.com (Nov. 13, 2008), http://www.upi.com/Health_News/2008/11/13/US-patients-suffer-more-medical-errors/UPI-50511226591663/.

16. PHILIP ASPDEN ET AL., PREVENTING MEDICATION ERRORS 1-2 (2006).

17. See generally LINDA T. KOHN ET AL., TO ERR IS HUMAN: BUILDING A SAFER HEALTH SYSTEM (2000).

18. *Id.*

19. See Mark A. Schuster et al., *How Good is the Quality of Health Care in the United States?* 76(4) MILBANK QUARTERLY 843, 888 (1998).

20. Elliott S. Fisher et al., *The Implications of Regional Variations in Medicare Spending. Part 1: The Content, Quality, and Accessibility of Care*, 138(4) ANNALS INTERNAL MED. 273 (2003); Elliott S. Fisher et al., *The Implications of Regional Variations in Medicare Spending. Part 2: Health Outcomes and Satisfaction with Care*, 138(4) ANNALS INTERNAL MED. 288 (2003).

fourth of procedures, and two-fifths of medications could be done without.²¹

Both patients and physicians express dissatisfaction with the quality of the American health system. In 2002, fifty-six percent of the public, forty-six percent of physicians, forty-eight percent of employers, fifty percent of health plan managers, and fifty-one percent of hospital managers felt that health care in the United States required “radical change.”²² According to a recent IOM report:

With the United States spending twice as much per capita as the average for most other developed countries—and 50 percent more than the second largest spending nation in the world—yet achieving poorer results than nearly two dozen other countries, the resources currently devoted to health are clearly sufficient to obtain much better outcomes.²³

The American health care crisis is worsening. Increasing demand, rising costs, and uneven quality are predicted to overwhelm the health system over the next fifteen years, creating massive financial burdens.²⁴ Americans should be receiving the highest quality care in the world for their substantial investment in health. The bottom line, however, is that health care in the United States fails to live up to its potential.

Causes of the Crisis

The reasons for the crisis are complex. In part, high costs and poor quality have been attributed to an absence of meaningful competition between providers.²⁵ Providers generally do not make information available on the costs of services and their outcomes, and this limits competition based on meaningful value. The health care industry has often been distinguished from businesses where comparative information is publically available, such as personal computing and telecommunications, and to businesses where competition has relentlessly improved consumer value.

21. Robert H. Brook, *Practice Guidelines and Practicing Medicine: Are They Compatible?* 262(21) JAMA 3027, 3028 (1989).

22. Harris Interactive Health Care Research, *Attitudes toward the United States' Health Care System: Long-Term Trends*, 2(17) HEALTH CARE NEWS 1, 2 (2002).

23. Vicki Weisfeld, *Summit on Integrative Medicine & the Health of the Public: Issue Background and Overview* (February, 2009), at <http://www.iom.edu/~media/Files/Activity%20Files/Quality/IntegrativeMed/IM20Summit20Background20Paper20Weisfeld2022309.pdf>, at 3.

24. *PRICEWATERHOUSE COOPERS'*, *supra note 4*, at 2.

25. Jost, *supra note 7*, at 549.

High health care costs are also a result of a large population with a high incidence of chronic disease.²⁶ At least 133 million people in the United States have one or more chronic conditions, which account for more than three-fourths of health care expenditures.²⁷ When the population is limited to seniors, the picture is worse: about eighty percent have at least one chronic health condition, and fifty percent have at least two chronic health conditions.²⁸ The crisis is expected to worsen as baby boomers age and begin to qualify for Medicare. This aging generation is predicted to drive additional cost escalation, precipitating intense pressure for cost shifting, price controls, rationing, and reduced services for even more Americans.²⁹

Despite amazing technological advances over the past century, conventional medical approaches have had limited success in managing chronic disease. Innovations such as antibiotics, vaccines, surgical transplants, and technological advances in diagnostics have resulted in extended life expectancy. Yet the very successes of allopathic medicine in treating conditions such as tuberculosis, smallpox, and trauma has led to a model of care focused on treating acute crises and late-stage disease. The mainstream medical model has fallen short in adequately addressing health maintenance, improving quality of life, and treating chronic, stress-related illness.

New health care technologies have also proven extremely expensive. The United States is the world leader in developing medical innovations, and new drugs and medical devices have contributed significantly to the increased cost of health care. In medicine, technological advances, such as magnetic resonance imaging (MRI) and robot-assisted surgery, have often resulted in increased rather than reduced prices, as well as increased rates of utilization.³⁰ Due to the design of the health care system, it is often possible for technology holders to charge monopoly prices for access to their developments. The United States has been criticized for lacking effective regulatory price controls in the private market,³¹ and unlike many

26. Neda Laiteerapong & Elbert S. Huang, *Health Care Reform and Chronic Diseases: Anticipating the Health Consequences*, 304(8) JAMA 899, 899 (2010).

27. Kenneth R. Pelletier et al., *Health and Medical Economics: Applications to Integrative Medicine*, Commissioned for the IOM Summit on Integrative Medicine and the Health of the Public (Feb. 2009), at 3-4.

28. Wan He et al., *Current Population Reports: 65+ in the United States: 2005*, U.S. CENSUS BUREAU (2005), <http://www.census.gov/prod/2006pubs/p23-209.pdf>, at 54.

29. MICHAEL E. PORTER & ELIZABETH OLMSTED TEISBERG, *REDEFINING HEALTH CARE: CREATING VALUE-BASED COMPETITION ON RESULTS* (2006).

30. Jost, *supra* note 7, at 548.

31. Jost, *supra* note 7, at 598.

other nations, the United States is forbidden by law from negotiating drug prices in the public market.

Even when appropriately prescribed, virtually all pharmaceutical-based interventions include some risk to the patient of side effects or complications, particularly over a long-term course of use. The more powerful the drug, the more likely it is to have harmful side effects. In 2000, the IOM reported that appropriately prescribed medications were responsible for approximately 106,000 deaths per year because of adverse effects.³² Medical malpractice litigation is also a factor in the increased cost of health care in the United States, although the direct cost of malpractice is less than two percent of health care costs.³³

The composition of the American physician workforce is also problematic. In comparison to other industrialized nations, the United States has a surplus of specialists, but not primary care physicians.³⁴ Research demonstrates that a greater availability of primary care physicians results in better health outcomes.³⁵ Primary care provides essential preventive care such as cancer screening, vaccination and lifestyle counseling to individuals before they develop disease. It also serves to identify early indications of conditions such as high blood pressure and diabetes, and to provide treatment before health and productivity are compromised and costly complications ensue.

Lifestyle data point to another cause of poor health outcomes and high medical costs.³⁶ Studies show the majority of Americans fail to maintain healthy practices. One study of more than 153,000 adults suggests that only three percent of Americans maintain a healthy weight, eat a minimum of five servings of fruits and vegetables a day, exercise at least five times a week for thirty minutes, and refrain from smoking.³⁷ Few adults in the United States follow clinical or public health recommendations for healthy living, and this may be directly responsible

32. See generally INSTITUTE OF MEDICINE (IOM), CROSSING THE QUALITY CHASM: A NEW HEALTH SYSTEM FOR THE 21ST CENTURY (2001).

33. Jost, *supra* note 7, at 548.

34. Barbara Starfield et al., *Contribution of Primary Care to Health Systems and Health*, 83(3) MILBANK QUARTERLY 457, 458 (2005).

35. *How Is a Shortage of Primary Care Physicians Affecting the Quality and Cost of Medical Care?*, AMERICAN COLLEGE OF PHYSICIANS, www.acponline.org/advocacy/where_we_stand/policy/primary_shortage.pdf.

36. Despite recent medical advances and research that have led to a greater understanding of the causes of poor health and disease, unexplained variations in health states remain. Not all illness is the result of behavioral or pathogenic influence; genetics also play a prominent role in human health. Furthermore, modern medicine still cannot explain the etiology of many conditions.

37. Matthew J. Reeves & Ann P. Rafferty, *Healthy Lifestyle Characteristics Among Adults in the United States, 2000*, 165 ARCH INTERN MED. 854, 854 (2005).

for negative health outcomes. Most people with chronic diseases such as cancer, diabetes and cardiovascular disease share common risk factors and lifestyle behaviors.³⁸ Tobacco use, poor diet and physical inactivity are leading contributors to overall mortality.³⁹

Patient Protection and Affordable Care Act

On March 23, 2010, President Obama signed the Patient Protection and Affordable Care Act into law. The Act introduces comprehensive health reform that will be implemented gradually over the next several years, with a focus on expanding health care coverage, controlling costs and generally improving the quality of health care.

The Act is predicted to expand health insurance coverage by adding 32 million covered individuals by 2019.⁴⁰ It creates an individual mandate which requires most American citizens and legal residents to obtain health insurance. Beginning in 2014, those who fail to obtain coverage, with certain exceptions, will be required to pay a tax penalty. To help individuals, families, and small businesses purchase insurance, the Act creates state-based insurance exchanges. It also provides premium and cost-sharing subsidies to individuals and tax credits to small businesses for obtaining coverage. In addition, the Act creates further incentives for employers to purchase health insurance for their employees. As an example of one negative incentive, the Act requires non-small business employers to pay penalties for employees who receive tax credits through an Exchange as a result of buying individual insurance. The Act also expands Medicaid to all individuals with incomes up to 133% of the federal poverty level. This measure is expected to provide Medicaid to an additional sixteen to twenty million individuals.⁴¹

The Act reforms common insurance industry practices that have historically created barriers to coverage. For example, it requires all policies to provide dependent coverage for children up to age twenty-six. The Act will also require insurers to accept all applicants, regardless of health status or preexisting conditions. It forbids canceling coverage except in cases of fraud, and also expands annual and lifetime benefit

38. Centers for Disease Control and Prevention, *Prevalence of Healthy Lifestyle Characteristics – Michigan, 1998 and 2000*, MORBIDITY AND MORTALITY WEEKLY REPORT, (Sept. 7, 2001), at <http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5035a3.htm>.

39. J. Michael McGinnis & William H. Foege, *Actual Causes of Death in the United States*, 270(18) JAMA 2207, 2207 (1993).

40. Connors & Gostin, *supra* note 6, at 2521.

41. *Id.*

limits. In addition, the Act contains a number of initiatives designed to improve health care quality. For example, it provides new sources of funding and support for comparative effectiveness research, home-based primary care, and increased reimbursement for primary care doctors. The Act emphasizes preventive, wellness, and public health approaches to care.

To finance health reform, the Act institutes multiple new tax changes. For example, in addition to the taxes designed to incentivize obtaining coverage, it imposes multi-billion dollar annual fees on the pharmaceutical and health insurance sectors, and excise taxes on sales of taxable medical devices. Because the main provisions of the Act have not yet been instituted, the actual effects of PPACA on spending are unclear. The official Congressional Budget Office (CBO) analysis indicates the Act will result in a modest deficit reduction over the next ten years; however, some experts have claimed it may actually add to the deficit.⁴²

Prevention and Wellness in PPACA

PPACA emphasizes prevention and wellness-based approaches to health care.⁴³ Preventive and wellness services constitute a diverse group of interventions. Preventive clinical services can include screening tests, immunizations, counseling and chronic disease management. Community-based services include screenings, health education, and group outreach programs. Wellness programs encourage healthy behaviors and lifestyles, including a focus on healthy diet, exercise and cessation of tobacco use. Despite controversy over the cost-effectiveness of preventive and wellness-based services, PPACA moves forward with a bold investment in these areas. Scheduled investments total \$15 billion over ten years on health care providers and programs that promote prevention, including \$500 million in fiscal year 2010 to increase the number of primary care professionals, improve community and clinical prevention efforts, and improve research and data collection.⁴⁴

PPACA requires Medicaid, Medicare and private health insurance plans to cover preventive care services recommended by the U.S. Preventive Services Task Force (USPSTF),⁴⁵ an independent panel of non-

42. See, e.g., Douglas Holtz-Eakin & Michael J. Ramlet, *Health Care Reform is Likely to Widen Federal Budget Deficits, Not Reduce Them*, 29 HEALTH AFFAIRS 1136 (2010).

43. *The Affordable Care Act's New Rules on Preventive Care and You*, HEALTHCARE.GOV (Jul. 14, 2010), <http://healthcare.gov/news/factsheets>.

44. Holly Korda, *Paying – and Playing – for Prevention: Is it Worth a Pound of Cure?* HEALTHY AMERICANS.ORG (Feb. 3, 2011), <http://healthyamericans.org/newsroom/news/?newsid=2169>.

45. U.S. Preventive Service Task Force, *USPSTF A and B Recommendations*, <http://www.uspreventiveservicestaskforce.org/uspstf/uspsabrecs.htm> (last visited Jan. 28, 2012). Most

federal experts in prevention and evidence-based medicine.⁴⁶ Both private and federal programs must eliminate patient cost-sharing for recommended preventive services and vaccines. Funding is also provided for community-based prevention and wellness programs, such as medication management services for patients with chronic diseases,⁴⁷ and health homes for Medicaid patients with chronic conditions.⁴⁸ PPACA establishes the National Diabetes Prevention Program, the National Prevention, Health Promotion and Public Health Council, and the Patient-Centered Outcomes Research Institute.⁴⁹

Primary care providers have long considered preventive and wellness approaches to care to be good medicine. Moreover, these approaches appeal to common sense. Preventing disease before it occurs avoids costs associated with treatment and disability—“an ounce of prevention is worth a pound of cure.” Recent promising data support the cost-effectiveness of preventive medicine. A study of the use of preventive services concluded that greater use of preventive services would save the U.S. public more than two million years of life and \$3.7 billion in personal health care spending annually.⁵⁰ The study found that the childhood immunization series, pneumococcal immunization for adults, discussion of daily aspirin use, smoking cessation advice and assistance, vision screening in older adults, alcohol screening and obesity screening all produced net medical savings.⁵¹ Other interventions, such as lifestyle modifications and early control of blood sugar, have been shown to decrease the incidence of diabetes and long-term complications.⁵² Wellness programs can reduce medical costs and strengthen workforce

insurers will have to cover recommendations A and B by the Task Force. The interim final regulations do not apply to grandfathered plans and issuers. Healthcare.gov, *Recommended Preventive Services*, <http://www.healthcare.gov/law/resources/regulations/prevention/recommendations.html> (last visited Jan. 28, 2012). The USPSTF defines A services as those for which “there is high certainty that the net benefit is substantial”, and B services as those for which “there is high certainty that the net benefit is moderate or there is moderate certainty that the net benefit is moderate to substantial.” U.S. Preventive Service Task Force, *Grade Definitions*, <http://www.uspreventiveservicestaskforce.org/uspstf/grades.htm> (last visited Jan. 28, 2012).

46. Patient Protection and Affordable Care Act (PPACA), H.R. 3590, 111th Cong. Section 4106 (2010).

47. *Id.* at Section 3503.

48. *Id.* at Section 2703.

49. See also ERIN D. WILLIAMS AND C. STEPHEN REDHEAD, CONG. RESEARCH SERV., PUBLIC HEALTH, WORKFORCE, QUALITY, AND RELATED PROVISIONS IN THE PATIENT PROTECTION AND AFFORDABLE CARE ACT (PPACA) 42, 48, 74, available at <https://www.aamc.org/download/130996/data/ph.pdf>.

50. Michael V. Maciosek et al., *Greater Use of Preventive Services in U.S. Health Care Could Save Lives At Little Or No Cost*, 29(9) HEALTH AFFAIRS 1656, 1656 (2010).

51. *Id.*

52. Louise B. Russell, *Prevention’s Potential for Slowing the Growth of Medical Spending*, (Oct. 2007), http://www.iuhcpar.rutgers.edu/downloads/nhc_report.pdf.

productivity.⁵³ One review of work site programs found average medical cost savings of \$3.48 per program dollar invested and reductions in absenteeism averaging savings of \$5.82 per dollar invested.⁵⁴

On the other hand, prevention can cost more money than it saves. Preventive treatments are provided to more people than would otherwise develop disease, some of whom will develop disease anyway. Some literature reviews have found that preventive treatments do not usually reduce medical costs.⁵⁵ Annual screenings, for example, result in more prescriptions, which increase drug costs, and more diagnostic tests, which generate additional treatment costs for newly discovered diseases. The net effect can be higher expenditures.⁵⁶ The bottom line is that accurately measuring the effects of preventive and wellness-based approaches to care is difficult. Medical care affects future earnings, quality of life, and productivity in uncertain ways. While statistics on preventive services tend to be lumped together, some preventive treatments are more effective than others.⁵⁷

III: THE CASE FOR COMPLEMENTARY AND ALTERNATIVE MEDICINE

Complementary and Alternative Medicine

The term complementary and alternative medicine refers to a group of health care systems, practices, and products not presently considered part of allopathic medicine.⁵⁸ Research has shown that consumers frequently use these treatments together with, rather than in place of, allopathic care.⁵⁹ Defining CAM positively, as opposed to what it is not, is difficult because CAM includes a changing and diverse group of practices. CAM systems and therapies may be grouped into broad categories such as natural products, mind-body medicine, and manipulative and body-based

53. *Id.*

54. S. Aldana, *Financial Impact of Health Promotion Programs: A Comprehensive Review of the Literature*, 15(5) AM. J. HEALTH PROMOTION 296, 296 (2001).

55. Russell, *supra* note 52, at 8.

56. *Id.* at 4.

57. Steven H. Woolf, *The Power of Prevention and What it Requires*, 299(20) JAMA 2437, 2437 (2008).

58. *What is Complementary and Alternative Medicine (CAM)?* NATIONAL CENTER FOR COMPLEMENTARY AND ALTERNATIVE MEDICINE (NCCAM), at <http://nccam.nih.gov/health/whatisacam/>.

59. D.M. Eisenberg et al., *Unconventional Medicine in the United States: Prevalence, Costs, and Patterns of Use*, 328(4) NEW ENG. J. MED. 246, 246 (1993). For this reason, the term *complementary and alternative medicine* is now primarily used to refer to non-allopathic therapies. Prior to wide adoption of the term CAM, the terms “unconventional” and “alternative” medicine were more frequently used to refer to non-allopathic forms of treatment.

practices.⁶⁰

Common value systems underlie CAM practices.⁶¹ These practices tend to be characterized by a holistic and highly individualized approach to patient care, an emphasis on maximizing the body's inherent healing ability, involving patients as active participants in their own care, addressing physical, mental, and spiritual attributes of a disease, and a strong emphasis on preventative medicine.⁶²

Because CAM practices share common features they tend to be considered as one large, homogenous group. However, CAM modalities are highly diverse. For example, CAM includes treatments as varied as herbal medicine, yoga, chiropractic and magnet therapy.⁶³ Therapies involve assorted levels of training and have different degrees of evidence-base and efficacy. In addition, CAM treatments are governed by a heterogeneous group of state and national policies and regulations and have a variety of associated cultural beliefs.

Traditional Medicine

Traditional medicine (TM) describes CAM practices with a long history of use.⁶⁴ TM frequently refers to medical knowledge developed by indigenous cultures that incorporates plant, animal and mineral-based medicines, spiritual therapies and manual techniques designed to treat illness or maintain well-being.⁶⁵ In many cultures, TM functions as a comprehensive system of health care refined over hundreds or even thousands of years. Some of the best known systems include traditional Chinese,⁶⁶ Indian (Ayurveda), and Arab (Unani) medicine. As opposed to

60. What is CAM? *supra* note 58.

61. Ryan B. Abbott et al., *Medical Student Attitudes Toward Complementary, Alternative, and Integrative Medicine*, 2011 EVIDENCE-BASED COMPLEMENTARY & ALTERNATIVE MED. 1, available at <http://www.hindawi.com/journals/ecam/2011/985243/abs/>.

62. *Id.*

63. What is CAM? *supra* note 58.

64. The World Health Organization (WHO) defines traditional medicine as "the sum total of knowledge, skills and practices based on the theories, beliefs and experiences indigenous to different cultures that are used to maintain health, as well as to prevent, diagnose, improve or treat physical and mental illnesses." World Health Organization (WHO), *Fact Sheet No. 134: Traditional Medicine* (Dec. 1, 2008), at <http://www.who.int/mediacentre/factsheets/fs134/en/index.html>.

65. World Health Organization (WHO), *Fact Sheet No. 134: Traditional Medicine* (May 2003), at <http://www.who.int/mediacentre/factsheets/2003/fs134/en/>.

66. A more specific example of such medicine, traditional Chinese medicine (TCM), is one the most widely used and studied systems. TCM, like many other forms of traditional medicine, differs from allopathic medicine in more than its techniques. Practitioners of TCM utilize a unique system of diagnosis that includes a comprehensive history of symptoms to arrive at a diagnosis of an underlying disharmony. Treatments focus on increasing the body's natural defenses through acupuncture, herbal medicine and physical manipulation. TCM considers that mind, body, spirit and the external environment all have a

relatively modern CAM practices, TMs have the benefit of substantial prior clinical use, as well as stronger cultural associations. Prior clinical use may provide evidence of safety and efficacy,⁶⁷ and cultural associations may result in traditional medicine being more readily accepted by some populations.⁶⁸

Although it is difficult to separate TM from CAM, CAM is the more inclusive term. Because American consumers utilize many different forms of CAM rather than a single kind of TM, this article focuses on CAM generally.

Integrative Medicine

Integrative medicine incorporates aspects of both CAM and allopathic medicine.⁶⁹ Generally, it combines allopathic treatments with CAM therapies that have high-quality scientific evidence of safety and effectiveness.⁷⁰ However, like CAM, the practice of integrative medicine is diverse. Specific techniques of CAM can be integrated into a disease-centered model. For example, an orthopedic surgeon may use acupuncture locally to reduce inflammation. This model of integration has resulted in some CAM techniques, such as patient support groups, becoming mainstream.⁷¹

Beyond a piecemeal absorption of CAM modalities into an allopathic model of medicine, integrative medicine may provide a new paradigm that incorporates core CAM values.⁷² For example, integrative medicine may be characterized by a humanistic, relationship-centered, partnership approach to care, a focus on biological, psychological, social, and spiritual

strong role in creating health or disease. Patients are made active participants in their own care through recommendations for lifestyle changes, body-mind exercises such as Tai Chi and Qi Gong, and nutrition and dietary therapy. *See generally* GIOVANNI MACIOCA, *THE FOUNDATIONS OF CHINESE MEDICINE: A COMPREHENSIVE TEXT FOR ACUPUNCTURISTS AND HERBALISTS*, 12 (2nd ed., Churchill Livingstone 2005).

67. Specific Directive (2004/24/EC), 2004 O.J. (L 136) 85 (EC) (hereinafter DTHMP); Directive on Traditional Herbal Medicinal Products amending, as regards traditional herbal medicinal products, Directive 2001/83/EC.

68. World Health Organization (WHO), *WHO Traditional Medicine Strategy 2002-2005* (2002), at 1 (hereinafter WHO TM Strategy).

69. The University of California at Los Angeles (UCLA) Center for East-West Medicine (CEWM) practices integrative clinical medicine. The CEWM seeks to merge the principles and techniques of traditional Chinese medicine and conventional medicine to develop a new integrative East-West medical paradigm. The Center's clinic represents an innovative outpatient treatment model in which the two medical systems are integrated within a single clinical environment where acupuncturists and medical doctors work together at all stages of patient care and management. *See generally* UCLA CENTER FOR EAST-WEST MEDICINE, <http://www.cewm.med.ucla.edu/>.

70. What is CAM? *supra* note 58.

71. *See generally id.*

72. Abbott, *supra* note 61, at 2.

influences to pathology, and an emphasis on providing hope, education and therapeutic approaches that match an individual's world-view.⁷³

CAM and the Public

CAM use in the United States is significant, both in terms of the number of people using CAM and in the out-of-pocket costs they are willing to incur for CAM products and services. Mainstream awareness of the resurgence⁷⁴ of non-allopathic treatments began with a study published in the *New England Journal of Medicine*, which reported that one-third of American adults had used at least one alternative therapy in 1990.⁷⁵ The study reported that the estimated number of visits made in 1990 to providers of unconventional therapy was greater than the number of total visits to primary care medical doctors nationwide, and the amount spent out-of-pocket for all hospitalizations.⁷⁶ Follow-up studies showed even higher levels of CAM use. By 1997, over forty-two percent of the population had used at least one form of CAM, and the industry had grown to \$21.2 billion in annual sales.⁷⁷

The most current and comprehensive studies on Americans' use of CAM were conducted through the 2002 and 2007 National Health Interview Surveys (NHIS). The studies found that nearly forty percent of adults use some form of CAM.⁷⁸ Americans spent an estimated \$33.9 billion out-of-pocket on CAM products and services during the prior year, accounting for 11.2% of total out-of-pocket health care expenditures.⁷⁹ Outside of the United States, the use of CAM is even more significant.⁸⁰ The global use of CAM is testament to the popular belief that CAM treatments are an effective form of health care.

73. *Id.*

74. In *The Politics of Healing*, Robert D. Johnston questions the conventional narrative that in the decades before World War II, "established medicine was supposedly taking all before it, the years when the tremendous ferment of the nineteenth-century alternative medicine world sickened and died." He argues instead that "alternatives did not just survive; they often thrived" until the renaissance of CAM over the last three decades. ROBERT D. JOHNSTON, *THE POLITICS OF HEALING*, 6, (2004).

75. Eisenberg, *supra* note 59, at 246.

76. *Id.*

77. See David M. Eisenberg et al., *Trends in Alternative Medicine Use in the United States: Results of a Follow-up National Survey 1990-1997*, 280(18) *JAMA* 1569, 1571, 1573 (1998); see also J.A. Astin, *Why Patients Use Alternative Medicine: Results of a National Survey*, 279(19) *JAMA* 1548 (1998).

78. Patricia M. Barnes et al., *Complementary and Alternative Medicine Use Among Adults and Children: United States, 2007*, NATIONAL HEALTH STATISTICS REPORTS, 1 (Dec. 10, 2008).

79. *Research Spotlight, National Survey Reports on Consumer Spending for CAM Products and Services*, NATIONAL CENTER FOR COMPLEMENTARY AND ALTERNATIVE MEDICINE (NCCAM), <http://nccam.nih.gov/research/results/spotlight/123109.htm> (last visited Jan. 28, 2012).

80. Ryan Abbott, *The Beijing Declaration—A Landmark for Traditional Medicine*, 13(1) *ICTSD NEWS & ANALYSIS* (2009).

CAM and the Government

In 1991, Senator Tom Harkin, Chair of the Appropriations Subcommittee that distributes funding for the National Institutes of Health (NIH), held congressional hearings on the use of CAM.⁸¹ After the hearings, a bipartisan majority of committee members assigned two million dollars of discretionary funding to set up an Office of Alternative Medicine (OAM) at the NIH.⁸² Over the years, Congress steadily increased funding for the OAM, which became the National Center for Complementary and Alternative Medicine (NCCAM) in 1998. NCCAM's current mission is to "to explore CAM healing practices in the context of rigorous science, train CAM researchers, and disseminate authoritative information to the public, health care professionals, and policy makers."⁸³ This year, the NCCAM budget proposal requests over \$132 million.⁸⁴ In the past decade it has funded more than 2,500 research projects, resulting in more than 3,300 scientific articles in peer-reviewed journals.

Senator Harkin, along with Senator Orrin Hatch, also played a major role in the adoption of the Dietary Supplement Health and Education Act (DSHEA) in 1994.⁸⁵ DSHEA created a new framework for the regulation of dietary supplements,⁸⁶ focused on ensuring widespread consumer access. Senators Harkin and Hatch teamed up once again to successfully lobby for creation of a White House Commission on Complementary and Alternative Medicine in 2000.⁸⁷ The Commission provided the President with recommendations to ensure that public policy maximizes the potential benefits of CAM to all citizens.⁸⁸ A final report of the Commission issued

81. Mary Ruggie, *Mainstreaming Complementary Therapies: New Directions in Health Care*, 24 HEALTH AFFAIRS 980, 982 (2005).

82. Originally established as the Office of Unconventional Medicine, it was later renamed the Office of Alternative Medicine. *See id.*

83. Research Spotlight, *supra* note 79.

84. Budget Request for Fiscal Year 2011: Before the House Subcommittee on Labor-HHS-Education Appropriations, 111th Cong. (2010) (statement of Josphine P. Briggs, M.D., Director of the National Center for Complementary and Alternative Medicine), *available at* <http://nccam.nih.gov/about/offices/od/directortestimony/0410.htm>; Solving the Small Business Health Care Crisis: Lowering Costs and Covering the Uninsured : Before the Senate Committee on Small Business, 109th Cong. 1 (2005) (statement of William N. Lindsay, III, former Chair of the National Small Business Association (NSBA)).

85. Johnston, *supra* note 74, at 4.

86. Nonvitamin/nonmineral products are considered to be CAM by NCCAM. *See* NCCAM.NIH.GOV, <http://nccam.nih.gov/health/whatiscam/#natural> (last visited Jan. 28, 2012). Some use of vitamin and mineral products can be considered CAM as well.

87. Johnston, *supra* note 74, at 4.

88. National Institutes of Health (NIH), Office of Dietary Supplements, *White House Commission on Complementary and Alternative Medicine Policy*, http://ods.od.nih.gov/Health_Information/White_House_CAM_Commission.aspx (last visited Jan. 28,

in March 2002 addressed the coordination of CAM research, the education and training of CAM providers, the provision of information about CAM to health care professionals, and the guidance regarding appropriate access and delivery of CAM.⁸⁹

CAM and U.S. Physicians

The conventional medical establishment has traditionally held negative attitudes toward CAM, and on multiple occasions physicians have attempted to restrict consumer access to CAM. For example, in 1963 the AMA formed a “Committee on Quackery” and began a campaign to eliminate non-allopathic forms of medicine, particularly chiropractic.⁹⁰ The AMA Principles of Medical Ethics forbade physicians to associate with chiropractors, teach in chiropractic schools, lecture at chiropractic conventions or accept patient referrals from a chiropractor.⁹¹ The AMA regularly referred to chiropractic medicine in disparaging terms, for example as an “unscientific cult.”⁹²

Ultimately, the AMA’s efforts to limit chiropractic medicine were unsuccessful. Chiropractors retained practice rights in all 50 states, and in 1972 Congress included chiropractic in both the Medicare and Medicaid programs.⁹³ In 1974, the U.S. Office of Education began accrediting chiropractic colleges, and in 1985 chiropractors were given their first hospital privileges.⁹⁴ In 1976, a group of chiropractors sued the AMA and other medical associations for unreasonably restraining trade as a result of their boycott of chiropractic medicine.⁹⁵ In 1987, Judge Susan Getzendanner, United States District Judge for the Northern District of Illinois Eastern Division found the AMA guilty of violating the Sherman Antitrust Act and guilty of conspiracy against chiropractors. The Court issued a permanent injunction against the AMA and required The Journal of the American Medical Association to publish the court’s judgment.⁹⁶ In 1990, the 7th United States Circuit Court of Appeals affirmed the lower

2012).

89. *Id.*

90. LYNDA W. FREEMAN, *MOSBY’S COMPLEMENTARY AND ALTERNATIVE MEDICINE, A RESEARCH BASED APPROACH*, 313, 2d ed., (Mosby, 2004).

91. *Id.*

92. *Wilk v. American Medical Association*, 671 F. Supp. 1465, 1467 (N.D. Ill. 1987).

93. PETER CONRAD, *THE SOCIOLOGY OF HEALTH AND ILLNESS*, 268, 8th ed., (Catherine Woods, 2009).

94. *Id.*

95. *Wilk v. American Medical Ass’n*, 735 F.2d 217, 7th Cir. 1983. The plaintiffs lost their first trial in 1981, but obtained a new trial on appeal in 1983 because of improper jury instructions and the admission of improper evidence.

96. *Wilk v. American Medical Ass’n*, 671 F. Supp. 1465 (N.D. Ill. 1987).

Court's decision, and the U.S. Supreme Court later denied certiorari.⁹⁷

More recently, research on physician attitudes has revealed a substantial change in attitudes toward CAM.⁹⁸ A national survey of family practitioners and internists, published in 1995, found “surprising[ly] high” support for patients’ use of CAM and referrals to CAM practitioners.⁹⁹ Another survey, conducted in 2004 among practicing staff internists in the Department of Medicine at the Mayo Clinic, found that 44 percent of physicians stated that they would refer a patient if a CAM practitioner were available at their institution, and 57 percent thought that incorporating CAM therapies would have a positive effect on patient satisfaction.¹⁰⁰ In 2009, the largest national survey of medical students found that three-quarters of study participants felt conventional Western medicine would benefit by integrating more CAM therapies and ideas.¹⁰¹ Sixty-one percent of respondents stated that their CAM-related medical education was inadequate, and 38 percent reported having received treatment from a CAM provider (an acupuncturist, chiropractor, etc.).¹⁰² The change in attitude has been attributed to a number of different factors, including increased awareness of patient use of CAM, an improved evidence base for CAM and the role of organizations such as NCCAM.¹⁰³

Along with the increased use of CAM and changing physician attitudes, a growing number of academic medical centers and community hospitals have begun offering CAM services. All 18 hospitals on *U.S. News*' most recent “America’s Best Hospitals” provide CAM services.¹⁰⁴

97. *Wilk v. American Medical Association*, 895 F.2d 352 (7th Cir. 1990).

98. One of the highest profile endorsements of CAM by the conventional medical establishment occurred in February 2009, when the Institute of Medicine sponsored *The Summit on Integrative Medicine and Health of the Public*. The event, held by America’s premier advisor on health care, was the most prominent domestic gathering of influential policymakers, academics, researchers and clinicians to promote integrative medicine. The IOM summit brought together leaders in the field of integrative medicine, CEOs of healthcare groups, physicians interested in the practice of integrative medicine, CAM practitioners, and directors of patient advocacy organizations. A summary of the summit was released in November 2009. Andrea Shultz et al., *Integrative Medicine and the Health of the Public: A Summary of the February 2009 Summit*, 3(4) INST. MED. 495 (2009).

99. D.L. Blumberg et al., *The Physician and Unconventional Medicine*, 1(3) ALTERNATIVE THERAPIES HEALTH & MED. 31, 31 (1995).

100. D.L. Wahner-Roedler et al., *Physicians’ Attitudes Toward Complementary and Alternative Medicine and Their Knowledge of Specific Therapies: A Survey at an Academic Medical Center*, 3 EVIDENCE-BASED COMPLEMENT ALTERNATIVE MED. 495, 495 (2006).

101. Abbott, *supra* note 80, at 7.

102. *Id.*

103. Mary Ruggie, *Mainstreaming Complementary Therapies: New Directions in Health Care*, 24 HEALTH AFFAIRS 980, 981-83 (2005).

104. Avery Comarow, *Top Hospitals Embrace Alternative Medicine*, U.S. NEWS, HEALTH (Jan. 9, 2008), <http://health.usnews.com/health-news/managing-your-healthcare/pain/articles/2008/01/09/embracing-alternative-care.html> (last visited Jan. 28, 2012).

Considering the University of California health care system as a case-in-point, UC Los Angeles,¹⁰⁵ UC San Francisco, and UC Irvine have prominent centers for integrative medicine.¹⁰⁶ In addition, all of these universities have substantial research programs investigating the efficacy and scientific mechanisms of CAM.

Changing physician attitudes may be due in part to a significant increase in the number of CAM articles in medical literature. A literature review in 1999 identified 33,000 CAM articles published in medical journals in a thirty-year period, with gradual increases from 1966 to 1996.¹⁰⁷ A second study found more than 20,000 CAM articles published in medical journals during the five-year period from 1997 to 2002, also with a significant upward trend over time.¹⁰⁸ A third study that looked at CAM articles in five top general medical journals over a 35-year period (1965–1999) found a steady stream of attention to CAM throughout the period, with a dramatic increase during the 1990s.¹⁰⁹ The study also found a consistent change in tone. According to the authors, “articles written in the early period employ a biting negative, almost combative tone, while later articles discuss CAM with objective disinterest.”¹¹⁰

Benefits of Complementary and Alternative Medicine

Scientific evidence is increasing that some CAM practices are

105. UCLA, for example, has a history of research in integrative medicine dating back to the 1970s. In 2004, the UCLA Collaborative Centers for Integrative Medicine (CCIM) was established, which incorporates multiple centers for integrative medicine as well as a large network of clinicians, educators, researchers, and policymakers. UCLA Collaborative Centers for Integrative Medicine (April 1, 2011), <http://www.ccim.med.ucla.edu> (last visited Jan. 28, 2012). Its membership includes groups at UCLA such as the Center for Human Nutrition and the Stiles Program in Integrative Oncology. The CCIM sponsors public and professional education, facilitates research, and promotes appropriate practice of complementary, alternative, and integrative medicine. The CCIM also represents UCLA in the Consortium of Academic Health Centers for Integrative Medicine (CAHCIM). CAHCIM includes fifty of the major university medical schools in the United States and Canada that have integrative medicine programs. Consortium of Academic Health Centers for Integrative Medicine (May, 2009), *About Us*, <http://www.imconsortium.org/about/home.html> (last visited Jan. 28, 2012).

106. The largest centers for integrative medicine at UCSF, UCLA and UCI respectively are the UCSF Osher Center for Integrative Medicine (<http://www.osher.ucsf.edu/>), the UCLA Center for East-West Medicine (<http://www.cewm.med.ucla.edu/>) and the UCI Susan Samueli Center for Integrative Medicine (<http://www.sscim.uci.edu/>). However, while these are the largest centers at their institutions, other clinical centers exist for integrative practice, traditional practice groups may incorporate CAM treatments, and individual physicians may incorporate elements of CAM. UC San Diego has recently launched its own Center for Integrative Medicine.

107. Joanne Barnes et al., *Articles on complementary medicine in the mainstream medical literature: an investigation of MEDLINE, 1966 through 1996* 1999(159) ARCH INTERN MED. 1721 (2011).

108. Roberto Raschett et al., *Complementary and Alternative Medicine in the Scientific Literature*, 11(1) J. ALTERNATIVE & COMPLEMENTARY MED. 209, 209 (2005).

109. Conrad, *supra* note 93, at 264.

110. *Id.*

effective forms of treatment. To consider acupuncture as a case-in-point, a national expert panel of the National Institutes of Health concluded as early as 1998 that, “promising results have emerged, for example, showing efficacy of acupuncture in adult postoperative and chemotherapy nausea and vomiting and in postoperative dental pain. There are other situations such as addiction, stroke rehabilitation, headache, menstrual cramps, tennis elbow, fibromyalgia, myofascial pain, osteoarthritis, low back pain, carpal tunnel syndrome, and asthma, in which acupuncture may be useful as an adjunct treatment or an acceptable alternative or be included in a comprehensive management program.”¹¹¹ In 2002, the World Health Organization (WHO) released *Acupuncture: Review and analysis of reports on controlled clinical trials*, which identified 28 conditions for which “acupuncture has been proved—through controlled trials—to be an effective treatment.”¹¹² In recent years, there has been a significant increase in the quantity of research conducted to evaluate the effects of acupuncture. A search for “acupuncture” in PubMed generates more than 16,000 results.

Some large-scale clinical studies have validated the efficacy of acupuncture.¹¹³ For example, an NCCAM-sponsored study that examined 570 patients with osteoarthritis of the knee determined that patients who received acupuncture improved in function, pain, and global assessment compared to patients who received a placebo treatment. The study concluded that acupuncture seems to provide improvement in function and pain relief as a therapy for osteoarthritis of the knee.¹¹⁴ Literature reviews, which examine clinical studies in the aggregate, have positively concluded acupuncture may be effective for various clinical conditions.¹¹⁵ For

111. See generally *Acupuncture*, NATIONAL INSTITUTES OF HEALTH CONSENSUS DEVELOPMENT CONFERENCE STATEMENT (Nov. 3, 1997), <http://consensus.nih.gov/1997/1997acupuncture107html.htm>.

112. *Acupuncture: Review and Analysis of Reports and Controlled Clinical Trials*, WORLD HEALTH ORGANIZATION, whqlibdoc.who.int/publications/2002/9241545437.pdf (last visited Jan. 28, 2012).

113. A randomized controlled trial of 401 patients with chronic headaches found that “acupuncture leads to persisting, clinically relevant benefits for primary care patients with chronic headache, particularly migraine.” See generally Andrew J. Vickers, *Acupuncture for Chronic Headache in Primary Care: Large, Pragmatic, Randomised Trial*, 328(7442) *BMJ* 744 (2004).

114. Brian M. Berman et al., *Effectiveness of Acupuncture as Adjunctive Therapy in Osteoarthritis of the Knee: A Randomized, Controlled Trial*, 141(12) *ANNALS INTERNAL MED.* 901 (2004).

115. A 2010 review of pooled data from high-quality randomized controlled trials comparing acupuncture to sham acupuncture for chronic pain found that “acupuncture is more than a placebo for commonly occurring pain conditions.” Ann Hopton & Hugh MacPherson, *Acupuncture for Chronic Pain: Is Acupuncture More than an Effective Placebo? A Systematic Review of Pooled Data from Meta-analyses*, 10(2) *PAIN PRACT.* 94, 94 (2010). Sham acupuncture is a placebo control designed to use techniques that are not intended to stimulate known acupuncture points. However, this is a controversial control as sham acupuncture may have a greater effect on no treatment controls than pharmacological placebos. See K. Linde et al., *Are Sham Acupuncture Interventions More Effective than (other) Placebos? A Re-analysis of Data from the Cochrane Review on Placebo Effects*, 17(5) *FORSCH KOMPLEMENTMED.* 259, 259 (2010).

example, a 2009 Cochrane review of acupuncture for tension-type headache evaluated eleven trials with 2,317 participants and concluded that “acupuncture could be a valuable non-pharmacological tool for patients with frequent episodic or chronic tension-type headaches.”¹¹⁶ The study noted that until the addition of recent evidence, data was insufficient to support a recommendation for the use of acupuncture in the treatment of headache.¹¹⁷

While rigorous scientific research on the efficacy of most CAM treatments is lacking, traditional forms of CAM are generally supported by extensive clinical practice. Traditional Chinese herbal medicine, for example, has been used and refined over literally thousands of years. A long history of use, while not the same as a clinical research study, provides evidence of safety and efficacy.¹¹⁸ One of the most prominent acknowledgements of the traditional evidence-base for CAM was the decision by the European Medicines Agency (EMA), the centralized regulatory agency responsible for the approval of therapeutic goods in the European Union, to accept traditional use as a basis for regulatory approval of traditional medicine. The special approval process enables “products that have been in long-standing traditional medicinal use to be registered under a simplified procedure because their safety and efficacy can be deduced from their long standing use in the specified conditions of use.”¹¹⁹ It also reflects an awareness of the substantial problems of attempting to evaluate some CAM treatments with standardized scientific models.

For both short and long term outcomes, acupuncture showed significant superiority over placebo for knee pain and headache. *Id.* Another systematic review of randomized controlled trials of traditional Chinese medicine (primarily acupuncture) for fibromyalgia evaluated twenty-five studies with 1,516 participants and concluded “TCM therapies appear to be effective for treating [fibromyalgia].” Cao H. et al., *Traditional Chinese Medicine for treatment of fibromyalgia: a systematic review of randomized controlled trials*, 16(4) J. ALTERNATIVE & COMPLEMENT MED. 397, 397 (2010). Unfortunately, the vast majority of reviews of acupuncture conclude not that acupuncture is likely to be effective or ineffective, but rather that research is insufficient to generate a recommendation. See, e.g., Ping Wu et al., *Acupuncture in Poststroke Rehabilitation: A Systematic Review and Meta-Analysis of Randomized Trials*, 41 STROKE e171, e171 (2010). Research in this area has been limited due to inadequate resources, bias and poor methodology.

116. Linde K et al., *Acupuncture for Tension-type Headache*, 1 COCHRANE DATABASE SYST. REV. Art. No. CD007587 (2009).

117. *Id.*

118. The EMA states that in the case of traditional herbal medicines, “the long tradition makes it possible to suppress the need for clinical data, in so far as the efficacy of the medicinal product is plausible on the basis of its long-standing use and experience as testified by bibliographic or expert evidence.” Specific Directive (2004/24/EC) amending, as regards traditional herbal medicinal products, Directive 2001/83/EC on the community code relating to medicinal products for human use, 2004 O.J. (L 136) p. 85-90, Preamble paragraph (5).

119. Specific Directive (2004/24/EC) amending, as regards traditional herbal medicinal products, Directive 2001/83/EC on the community code relating to medicinal products for human use, 2004 O.J. (L 136) p. 85-90, at 87.

CAM has benefits beyond improving specific disease outcomes. Treatments may globally improve health related quality of life.¹²⁰ CAM is also generally non-invasive with a preventive focus, thereby limiting adverse effects from treatment and helping to prevent disease before it occurs.¹²¹ In addition, it may be useful where access to conventional medicine is limited. Partially as a result of the high cost of investment, there are still many conditions that lack effective conventional treatment, particularly for diseases such as malaria that exert their strongest impact on disadvantaged regions. Even for conditions where effective treatments exist, essential drugs are often not affordable or available to the populations that need them most. Lack of adequate coverage in the U.S. has been linked with non-compliance, as patients fail to fill their prescriptions because of the financial burden. In some instances, the cost of complications from non-compliance may outstrip the cost of treatment. By contrast, for many of these conditions, CAM treatments already exist and are in wide use. CAM treatments may also help patients who experience only partial relief of their symptoms from medication or who may be unable to tolerate pharmaceutical intervention.¹²²

The potential benefits of CAM are many. On the whole, the WHO has acknowledged that “traditional, complementary, or alternative medicine has many positive features, and that traditional medicine and its practitioners play an important role in treating chronic illnesses, and improving the quality of life of those suffering from minor illness or from certain incurable diseases.”¹²³

Cost Effectiveness

Another attraction of complementary and alternative medicine is its potential to improve disease outcomes and quality of life at relatively low

120. Tai Chi, for example, has been shown to be effective in the care of chronic headaches. Dieter Melchart et al., *Acupuncture for Chronic Headaches—An Epidemiological Study*, 46(4) HEADACHE 632-641, 632 (2006). In this study, Tai Chi was shown to not only improve headache impact, but also to decrease general pain and fatigue, and improve energy, social functioning, emotional well-being, and mental health. An NCCAM sponsored review of 66 randomized controlled trials of tai chi and qi gong with a total of 6,410 participants found that Tai Chi may benefit bone health, cardiopulmonary fitness, balance and factors associated with preventing falls and quality of life. See generally R Jahnke et al., *A Comprehensive Review of Health Benefits of Qigong and Tai Chi*, 24(6) AM. J. HEALTH PROMOTION e1 (2010).

121. See generally Patricia M. Herman et al., *Is Complementary and Alternative Medicine (CAM) Cost-effective? A Systematic Review*, 5 BMC COMPLEMENT ALTERNATIVE MED. 11 (2005); see generally AR White & E Ernst, *Economic Analysis of Complementary Medicine: A Systematic Review*, 8 COMPLEMENTARY THERAPIES MED. 111 (2000).

122. WHO, *supra* note 68, at 5.

123. *Id.*

cost. CAM treatments are typically low-tech, high-touch in nature and rely on inexpensive manual therapies and natural products in the public domain. The disparity in cost between conventional medicine and CAM is well-illustrated in the case of medication therapies. Developing a new chemical drug is an extremely expensive and time-consuming process. Moving a new compound from discovery through clinical trials and approval takes many years, risks a high chance of failure, and on average costs hundreds of millions of dollars.¹²⁴ These costs are passed on to consumers and result in prescription medicines being a significant factor in the total cost of healthcare—around 13 percent.¹²⁵ Over the past decade, the percentage of Americans using prescription drugs on a regular basis has increased. The percentage of Americans using least one prescription drug a month has increased from 44% to 48%, two or more drugs from 25% to 31%, and five or more drugs from 6% to 11%.¹²⁶ In 2008, spending for prescription drugs was \$234 billion, which is more than double what was spent in 1999.¹²⁷

The research that has been conducted on the cost-effectiveness of CAM has generally been positive.¹²⁸ A 2005 review study found a total of 56 economic evaluations of CAM covering a range of therapies and conditions. Only 14 of these were found to meet quality requirements of systematic reviews of economic evaluations in conventional medicine. The report found several “CAM therapies that may be considered cost-effective compared to usual care for various conditions: acupuncture for migraine, manual therapy for neck pain, spa therapy for Parkinson’s, self-administered stress management for cancer patients undergoing chemotherapy, pre- and post-operative oral nutritional supplementation for

124. Joseph A. DiMasi et al., *The Price of Innovation: New Estimates of Drug Development Costs*, 22 J. HEALTH ECON. 151, 151 (2003).

125. *Focus on Prices and Spending*, 1 U.S. BUREAU OF LABOR STATISTICS 8 (2010), at http://www.bls.gov/opub/focus/volume1_number8/cex_1_8.pdf.

126. Qiuping Gu et al., *Prescription Drug Use Continues to Increase: U.S. Prescription Drug Data for 2007–2008*, NCHS Data Brief, No. 42 (Sept. 2010), at 1.

127. *Id.*

128. For example, England’s National Health Service funded a study in 2006 which found that patients receiving acupuncture for low back pain experienced less pain than those receiving standard care, and were significantly more likely to be “very satisfied” with their treatment. See generally KJ Thomas et al., *Randomised Controlled Trial of a Short Course of Traditional Acupuncture Compared with Usual Care for Persistent Non-specific Low Back Pain*, 333 BMJ 623 (2006). The study reported its cost-benefit analysis in terms of Quality Adjusted Life Years (QALY), a measure of the benefits provided by a medical procedure in quality and quantity of life gained. Acupuncture was found to be both clinically effective and economically desirable, with the cost per QALY gained conservatively estimated to be \$7,921. This figure was well below the threshold used to decide whether the National Health Service could afford to pay for a health technology. The acupuncture group was also less likely to worry about their back pain, use pain medications, or experience pain.

lower gastrointestinal tract surgery, biofeedback for patients with ‘functional’ disorders (e.g., irritable bowel syndrome), and guided imagery, relaxation therapy, and potassium-rich diet for cardiac patients.”¹²⁹ A revised version of this study, still in preparation, has found 156 published economic evaluations of CAM, including 108 full evaluations and 48 partial evaluations.¹³⁰ Evidence suggests that acupuncture,¹³¹ chiropractic,¹³² and integrative care¹³³ are likely to be cost-

129. Herman, *supra* note 121, at 1. It states that, “Whereas the number and quality of economic evaluations of CAM have increased in recent years and more CAM therapies have been shown to be of good value, the majority of CAM therapies still remain to be evaluated.” *Id.*

130. Kennet R. Pelletier et al., *Health and Medical Economics: Applications to Integrative Medicine*, Commissioned for the IOM Summit on Integrative Medicine and the Health of the Public (Feb. 2009), at 34.

131. A 2009 review that assessed over 100 studies of economic evaluations of CAM found fifteen full economic evaluations of acupuncture in the past ten years. *Id.* at 36. Six of these had results that showed both health improvements and cost savings, and the remaining nine, all of which were randomized controlled studies, showed improved health outcomes without cost savings. *Id.* The remaining studies evaluated chiropractic care, mind-body medicine, homeopathy, and dietary supplements. The review concludes, “This review of published economic evaluations has highlighted a wide number of appropriate therapeutic approaches that might be included in an [integrative medicine] model. *Id.* at 38.

132. According to a 2007 study in the *Journal of Manipulative and Physiological Therapeutics*, chiropractors and other holistically-oriented physicians working as primary care providers (PCPs) have lower utilization costs and higher patient satisfaction levels than patients treated by conventional medical doctors. Richard L. Sarnat et al., *Clinical Utilization and Cost Outcomes from an Integrative Medicine Independent Physician Association: An Additional 3-year Update*, 30(4) J. MANIPULATIVE & PHYSIOLOGICAL THERAPEUTICS 263, 263 (2007). The study looked at data from an Independent Physicians Association (IPA) where chiropractors serve as first-contact PCPs and compared it to data from a conventional health maintenance organization (HMO). Patients visiting CAM-oriented PCPs experienced fewer hospitalizations, surgeries, and used fewer pharmaceuticals. The results were consistent with an earlier report published in 2004. Editorial, *DCs as Primary Care Providers: New Managed Care Study Finds Improved Patient Outcomes and Significant Cost Savings With DC Gatekeepers*, CHIROWEB.COM, www.chiroweb.com/archives/22/18/16.html. A study in the *Archives of Internal Medicine* examining the effect of access to chiropractic care on overall consumption of health care resources within a large managed-care system found that access to chiropractic care may reduce overall health care expenditures. See also P. Antonio et al., *Comparative Analysis of Individuals With and Without Chiropractic Coverage: Patient Characteristics, Utilization, and Costs*, 164 ARCH INTERN MED. 1985 (2004). It found that having chiropractic coverage was associated with a 1.6 percent decrease in total annual health care costs, and patients with back pain had lower utilization of x-rays, MRIs, surgery, and hospitalization for their back pain. *Id.* Additional studies report cost benefits of chiropractic care compared with conventional medical treatment for neuromuscular conditions in a review of literature. M. Smith & M. Stano, *Costs and Recurrences of Chiropractic and Medical Episodes of Low-back Care*, 20 J. MANIPULATIVE PHYSIOL THERAPY 5 (1997); H. Dean & R. Schmids, *A Comparison of the Cost of Chiropractors Versus Alternative Medical Practitioners*. Richmond: Virginia Chiropractic Association; 1992. However, a study by Carey, et al., found significantly higher health care costs for patients with chiropractic or orthopedic care for back pain (secondary to a greater number of visits) than for patients who received their back pain care from a primary care physician at a health maintenance organization. Timothy S. Carey et al., *North Carolina Back Pain Project, The Outcomes and Costs of Care for Acute Low Back Pain Among Patients Seen by Primary Care Practitioners, Chiropractors, and Orthopedic Surgeons*, 333 NEW ENG. J. MED. 913 (1995).

133. A 2010 report from The Bravewell Collaborative, *The Efficacy and Cost-Effectiveness of Integrative Medicine*, summarizes the information supporting an integrative approach to health care. See generally Erminia Guarneri et al., *The Efficacy and Cost-Effectiveness of Integrative Medicine: A Review of the Medical and Corporate Literature*, 6(5) J. Science & Healing 308 (2010). It finds that immediate and significant health benefits and costs savings could be realized by utilizing integrative lifestyle change

effective compared with conventional care.¹³⁴

Given the national shortage of primary care doctors, there is a need for additional health professionals to provide primary care. PPACA invests in nursing education and nurse-managed health clinics that provide primary care to vulnerable populations.¹³⁵ Appropriately-trained CAM providers may be a largely untapped resource in this regard.

Finally, because CAM therapies are generally non-invasive, they help avoid the human and economic costs of adverse effects from medical treatment, as well as the legal and administrative costs that can be associated with conventional therapies. In a domestic analysis of malpractice data, claims against chiropractors, massage therapists and acupuncturists were found to occur less frequently and involve less severe injury than claims against medical doctors. In a worldwide literature review, only 193 adverse events following acupuncture (including minor events such as bruising and dizziness) were identified within a 15-year period.¹³⁶ In considering whether to incorporate CAM into mainstream health care, providers and policy makers should keep in mind the core principle of nonmaleficence in medical ethics: that is, the duty to first do no harm.

programs for patients with chronic disease, integrative interventions for people experiencing depression, and integrative preventive strategies to support wellness in all populations. The report also summarizes some of the studies of integrative medicine and cost. For example, a 2009 review of more than 120 studies of comprehensive health management programs offered by employers showed that in 2005 the employers experienced an average 26% reduction in health care costs and an average \$5.81 returned for every \$1 invested in worksite health promotion initiatives. Seth Serxner et al., *Do Employee Health Management Programs Work?* 23(4) AM. J. HEALTH PROMOT 1 (2009). In another study, The Preventive Medicine Research Institute conducted a multisite trial with eight hospitals and determined that 80% of the participants in the comprehensive lifestyle change program were able to safely avoid heart surgery or angioplasty, saving almost \$30,000 per patient in the first year. D Ornish et al., *Can Lifestyle Changes Reverse Coronary Heart Disease? The Lifestyle Heart Trial*, 336(8708) LANCET 129, 129 (1990). According to The Bravewell Collaboration report, “Conventional therapies, such as pharmaceutical interventions or surgeries, typically treat symptoms but do not address the causes of most chronic disease, which are often rooted in unhealthy lifestyles and high stress levels.”

134. Much of the research of the benefits and cost-effectiveness of CAM is conducted outside of the U.S., where CAM plays a more significant role in national health care systems. Research conducted in China, Japan, South Korea and Brazil, all nations with a significant degree of integration of traditional medicine in national health care systems, may not be published in English or made accessible to U.S. researchers. For example, a 2000 study on the cost-effectiveness of CAM conducted for the Government of Peru and supported by WHO’s Regional Office for the Americas (PAHO) concluded that, in the treatment of nine selected conditions, the cost of using CAM was lower than the cost of providing conventional therapy, and that CAM was more effective with fewer side-effects. Convenio EsSalud OPS/OMS, *Cost-Effectiveness Study National Program of Complementary Medicine*, Seguro Social de EsSalud OPS/PER/00.15. Lima, Peru. 2000.

135. Bruce J. Douglas & Kelly McBeain, *The Patient Protection and Affordable Care Act – Improving the Health Care Workforce: “Physicians, Nurses, and Dentists” – Third in Series*, Larkin Hoffman Daly & Lindgren Ltd., http://www.larkinhoffman.com/news/article_detail.cfm?ARTICLE_ID=661 (last visited Jan. 28, 2012).

136. Herman, *supra* note 121, at 5.

Risks of Complementary and Alternative Medicine

Enthusiasm for the use of CAM should not be uncritical. Not all CAM treatments are effective.¹³⁷ For example, some studies have found no benefit from the use of Echinacea for the common cold. A study published in *The New England Journal of Medicine*, treated 399 participants with placebo or Echinacea beginning 7 days before exposure and found no change in the rate of infection, severity of symptoms, or inflammation.¹³⁸ Despite this negative research, in 2007, Echinacea was still the third most commonly used herbal supplement by adults and the first by children.¹³⁹ Still, other studies have found positive effects from the use of Echinacea, and NCCAM concludes that the results of Echinacea research have been mixed, but that any benefits are likely to be modest at best.¹⁴⁰ Negative

137. Another NCCAM funded project, the Ginkgo Evaluation of Memory (GEM) study, found that ginkgo did not lessen cognitive decline compared to placebo. The GEM study was a randomized, double-blind, placebo-controlled clinical trial of 3,069 adults conducted in multiple academic medical centers in the U.S. between 2000 and 2008. Beth E. Snitz et al., *Ginkgo Biloba for Preventing Cognitive Decline in Older Adults: A Randomized Trial*, 302(24) JAMA 2663, 2663 (2009). The study failed to find evidence of an effect on general cognitive decline, or specifically on memory, attention, visual-spatial construction, language or executive functions. Subsequent analyses based on data from the trial failed to find evidence that ginkgo reduced incidence of overall dementia or Alzheimer's dementia, Steven T. DeKosky et al., *Ginkgo Biloba for Prevention of Dementia*, 300(19) JAMA 2253, 2253 (2008), most cancer types, Mary L. Biggs et al., *Ginkgo Biloba and Risk of Cancer: Secondary Analysis of the Ginkgo Evaluation of Memory (GEM) Study*, 19(7) PHARMACOEPIDEMIOLOGY & DRUG SAFETY 694, 694, (2010), blood pressure/hypertension, Tina E. Brinkley et al., *Effect of Ginkgo Biloba on Blood Pressure and Incidence of Hypertension in Elderly Men and Women*, 23(5) AM. J. OF HYPERTENSION 528 (2010), or cardiovascular events (heart attack and stroke), Lewis H. Kuller et al., *Does Ginkgo Biloba Reduce the Risk of Cardiovascular Events?* 3(1) CIRCULATION: CARDIOVASCULAR QUALITY & OUTCOMES 41, 41 (2010). However, subsequent analysis of the study's data did find that Ginkgo may reduce the risk of developing peripheral arterial disease, a potentially life-threatening condition affecting blood circulation. Lewis H. Kuller et al., *Does Ginkgo Biloba Reduce the Risk of Cardiovascular Events?* 3(1) CIRCULATION: CARDIOVASCULAR QUALITY & OUTCOMES 41, 41 (2010).

138. Ronald B. Turner et al., *An Evaluation of Echinacea Angustifolia in Experimental Rhinovirus Infections*, 353(4) NEW ENG. J. MED. 341, 341 (2005). These negative results have been validated by independent studies. A second study in *Annals of Internal Medicine* found Echinacea did not reduce the severity or duration of cold symptoms in a group of 142 college students with early cold symptoms. BP Barrett et al., *Treatment of the Common Cold with Unrefined Echinacea: A Randomized, Double-blind, Placebo-Controlled Trial*, 137(12) ANN INTERN MED. 939, 939 (2002). A study in the *Journal of the American Medical Association* found Echinacea did not reduce the severity or duration of cold symptoms in a group of 407 children, and that it was associated with increased risk of rash. JA Taylor et al., *Efficacy and Safety of Echinacea in Treating upper respiratory Tract Infections in Children: A Randomized Controlled Trial*, 290(21) JAMA 2821, 2821 (2003). A study published in 2010 and funded by NCCAM also evaluated the use of Echinacea as a treatment for the common cold. The study randomized 713 study participants to receive no pills, placebo, or Echinacea. The duration and severity of cold symptoms were measured twice a day for up to 2 weeks, and the patients who received Echinacea had no significant improvements. BP Barrett et al., *Echinacea for Treating the Common Cold*, 153 ANN INTERN MED. 769, 769 (2010).

139. *Research Spotlight, Three Studies Find Echinacea Ineffective Against the Common Cold*, NATIONAL CENTER FOR COMPLEMENTARY AND ALTERNATIVE MEDICINE, <http://nccam.nih.gov/research/results/spotlight/051805.htm> (last visited Jan. 28, 2012).

140. Josephine Briggs, *Echinacea – What Have we Learned and Where are we Going?* (Dec. 20, 2010), <http://nccam.nih.gov/about/offices/od/2010-12.htm> (last visited Jan. 28, 2012).

studies have been criticized for using different *Echinacea* species, parts of the *Echinacea* plant, doses and preparations.¹⁴¹

The use of CAM may delay the use of effective allopathic interventions, or it can directly cause adverse effects. While longstanding use sometimes provides evidence of safety, this type of evidence has limitations. In particular, adverse effects that occur infrequently or develop over long time periods may be challenging for traditional practitioners to identify.¹⁴² In the case of dietary supplements, health risks may be posed by drug-herb interactions,¹⁴³ and problems related to quality control.¹⁴⁴

141. NCCAM, *supra* note 137; Mark Blumenthal & Norman R. Farnsworth, *Echinacea Angustifolia in Rhinovirus Infections*, 353(11) NEW ENG. J. MED. 1971, 1971 (2005).

142. Peter A.G.M. De Smet, *Herbal Remedies*, 347 NEW ENG. J. MED. 2046, 2047-2048 (2002).

143. This is an under-investigated area and the true extent of most drug-herb interactions is unknown. The majority of the information on these interactions comes from case reports. Patients may be reluctant to report dietary supplement use to their physicians, and surveillance systems have experienced historic failures. A 2003 report by the Office of the Inspector General concluded that the then current surveillance systems probably detected less than 1% of all adverse effects from dietary supplements. Department of Health and Human Services, Office of the Inspector General, *Adverse Event Reporting for Dietary Supplements: An Inadequate Safety Valve*, OEL-01-00-00180 (April 2001), at <http://oig.hhs.gov/oei/reports/oei-01-00-00180.pdf>. Since mandatory reporting requirements went into effect in 2007, the FDA has experienced a substantial increase in the number of reported adverse effects. For example, the agency received 948 adverse event reports in a ten-month period during 2008, compared with 298 during the same time period in 2007. States Government Accountability Office (GAO), *Dietary Supplements: FDA Should Take Further Actions to Improve Oversight and Consumer Understanding*, GAO-09-250, Jan. 29, 2009, at 5-6. Of the 948 adverse event reports, 596 were mandatory reports of serious adverse events submitted by industry. The remaining 352 were voluntary reports of mild and moderate events submitted directly by health care practitioners and consumers. However, this still probably represents a significant underreporting of adverse effects. The FDA recently estimated 50,000 adverse effects occur yearly as a result of dietary supplement use. *Id.* To keep these risks in perspective, it should be noted that despite the widespread use of dietary supplements, reports of serious adverse effects are rare. DH Phua et al., *Dietary Supplements and Herbal Medicine Toxicities—When to Anticipate Them and How to Manage Them*, 2 INT’L J. EMERG MED. 69, 69 (2009).

144. In a study of 59 dietary supplements with *Echinacea*, 10% were found to contain no *Echinacea*, and 48% of the samples with *Echinacea* did not contain the labeled species. CM Gilroy et al., *Echinacea and Truth in Labeling*, 163(6) ARCH INTERN MED. 699, 699 (2003). A different analysis of 25 ginseng herbal supplements found a 15 to 200-fold variation in the concentration of active ginseng ingredients. Martha R Harkey et al., *Variability in Commercial Ginseng Products: An Analysis of 25 Preparations*, 73 AM. J. CLINICAL NUTRITION 1101, 1101 (2001). More seriously, a significant number of herbal products have been found to contain pharmaceuticals. Edzard Ernst, *Adulteration of Chinese Herbal Medicines with Synthetic Drugs: A Systematic Review*, 252 J. INTERN MED 107, 107 (2002). In December 2008, the FDA issued a warning to consumers nationwide advising them to avoid a list of 60 dietary supplements that were found to contain undeclared drugs. An FDA analysis of these supplements uncovered active pharmaceutical ingredients far in excess of FDA-recommended levels, including an anti-seizure medication, a suspected carcinogen, and a drug not approved for marketing in the U.S. *FDA Expands Warning to Consumers About Tainted Weight Loss Pills List increases from 28 to 60 products; Agency seeking recalls*, FOOD AND DRUG ADMINISTRATION, <http://www.fda.gov/newsevents/newsroom/pressannouncements/2008/ucm116998.htm> (last visited Jan. 28, 2012). In 2005 researchers purchased 230 traditional Ayurvedic herbal medicines available online for sale in the U.S. and tested these products for the presence of heavy metals. Nearly 21 percent were found to contain lead, mercury or arsenic. Claims by manufacturers that they used Good Manufacturing Practices (GMP) or metal testing were not associated with a lower prevalence of heavy metals. RB Saper et al., *Lead, Mercury, and Arsenic in U.S. and Indian-manufactured Ayurvedic Medicines Sold via the Internet*, 300(8) JAMA 915, 915 (2008). The issue of adulteration and contamination,

IV: TOWARD NEW POLICIES

Given the current heightened public awareness and interest in health care, the U.S. Government has the opportunity to improve both CAM and mainstream medical care. The American public is already using CAM, but making choices without the guidance of valid scientific evidence. Greater integration of CAM with mainstream health care can produce value-based health care—improved quality at lower cost. In his second State of the Union address, President Obama declared that he was open to amending PPACA.¹⁴⁵

Reimbursement for Evidence-Based CAM

Evidence-based CAM treatments should be included in private and public insurance reimbursement. An independent panel of CAM experts is needed to conduct regular scientific reviews of CAM and to develop recommendations for which services to include in mandated reimbursement. This would be similar to the function performed by the USPSTF, and might be performed by either the USPSTF or through NCCAM. Mandating reimbursement for treatments that are found to be safe and effective would increase the use of treatments with proven benefits, stimulate additional CAM research, incentivize private investment in CAM, and improve existing CAM use by enhancing integration with conventional care.

Prior Efforts at Mandating CAM Reimbursement

Some state laws already mandate coverage for CAM services. In 1995, the State of Washington passed the “Every Category of Provider” (ECOP) law, and became the first state to require that insurance companies reimburse all licensed health care providers for treatment of covered medical conditions.¹⁴⁶ Under the ECOP law, “health carriers shall not

particularly from Asian sources, is not limited to herbal medicine. National attention has recently been focused on this matter in the aftermath of incidents related to infant formula, pet food, and toothpaste contamination.

145. *Coming Soon – PPACA in 3-D: Defunded, Delayed, Dismantled?*, CERIDIAN HEALTH CARE COMPASS, (Feb. 2011), at http://www.ceridian.com/employee_benefits_article/1,6266,15766-77009,00.html.

146. Shortly after its passage, the ECOP law was challenged in court by a consortium of 26 Washington State insurance carriers as a violation of the Employee Retirement Income Security Act (ERISA). In 1997, a Federal District Court ruled that ERISA preempted its implementation, but this decision was reversed by the Ninth Circuit Court of Appeals. The United States Supreme Court declined to reconsider the case. With the final avenue of appeal denied, the hold on implementation of the law was removed, and Washington

exclude any category of providers licensed by the State of Washington who provide healthcare services or care within the scope of their practice for conditions covered by basic health plan (BHP) services. . . If the BHP covers the condition, the carrier may not exclude a category of provider who is licensed to provide services for that condition, and is acting within the scope of practice, unless such services would not meet the carrier's standards. . ." Since 1983, Washington has required private health insurance companies to provide benefits for chiropractic services.¹⁴⁷ In 2000, the "Patient's Bill of Rights" act was passed and permitted patients to self-refer to chiropractors without a referral from an allopathic physician.¹⁴⁸ According to the Washington acupuncture association, the ECOP law is regularly challenged by a bill or rider, as insurance companies lobby to change it.¹⁴⁹

A study on the use of CAM providers by privately insured consumers in Washington found the number of people using CAM insurance benefits was substantial, but the effect on insurance expenditures was modest.¹⁵⁰ The study noted that insurance companies resisted providing coverage for CAM services in part due to fear that coverage would result in large and increasing expenditures, as had occurred with prescription drug coverage.¹⁵¹ However, the evidence in this study suggests this will not be the case. The study theorized the relatively minimal effect on expenditures was due to a narrow scope of practice for some CAM providers, relatively low rates of utilization compared to conventional care, and the lower cost of CAM.

Laws mandating insurance coverage for CAM services are not unique to Washington.¹⁵² Mandating reimbursement for acupuncture has been a frequent subject of legislation in California, where Assembly Bill 72 (AB72) is currently under consideration. AB72 requires every issuer of

Administrative Code Section 284-43-205 specified January 1, 2000 as the formal date for implementation.

147. Chiropractic care, coverage required, exceptions. WASH. REV. CODE § 48.44.310. (West, 2011).

148. WASH. REV. CODE § 48.43.515(5) (West, 2011); *see also* WASH. ADMIN. CODE § 284-43-251(3) (West, 2011).

149. *Background Information about Mandated Insurance Coverage for Acupuncture*, ACUPUNCTURE & ORIENTAL MEDICINE SOCIETY OF MASSACHUSETTS, <http://www.aomsm.onefireplace.org/Resources/Documents/MAAcupunctureInsuranceMandate.pdf> (last visited Jan. 28, 2012).

150. "Total expenditure per enrollee were \$2,589 of which \$75 (2.9%) was spent on CAM." William E. Lafferty et al., *Insurance Coverage and Subsequent Utilization of Complementary and Alternative Medicine (CAM) Providers*, 12(7) AM. J. MANAG CARE 397, 397 (2006).

151. *Id.* at 401.

152. *See* Carolyn A. Watts et al., *The Effect of Mandating Complementary and Alternative Medicine Services on Insurance Benefits in Washington State*, 10(6) J. ALTERN COMPLEMENT MED. 1001, 1002 (2004) (stating that in 2000, forty-one states mandated coverage of chiropractic services and eight states mandated coverage of acupuncture).

health insurance and health care service plan that provides coverage for hospital, medical, or surgical expenses to provide coverage for acupuncture.¹⁵³ The impartial California Health Benefits Review Program (CHBRP) conducted an evidence-based assessment of the medical, financial, and public health impacts of AB72 and found several conditions for which a preponderance of evidence suggests acupuncture is clinically effective and/or cost effective.¹⁵⁴ CHBRP estimated there would be a negligible change in utilization of acupuncture due to the mandate and a small increase in total net annual expenditures.¹⁵⁵ To become law, the bill must pass the state assembly and state senate before July, and it requires the approval of Governor Jerry Brown. Prior to AB72, a similar bill, AB52, passed the state assembly before being vetoed by former Governor Arnold Schwarzenegger. Prior to AB52, in 2001 Senate Bill 573 had also proposed mandated coverage for acupuncture.

Attempts to mandate coverage for CAM services have also been made at the Federal level. The Federal Acupuncture Coverage Act of 2009 attempted to provide coverage of acupuncture under Medicare and the Federal Employees Health Benefits Program (FEHB).¹⁵⁶ When the Act was first sponsored by Congressman Maurice Hinchey in 1993, it had five co-sponsors. It had 37 co-sponsors in 2009.¹⁵⁷

Conditioning Reimbursement on Evidence

Proposals to generally mandate coverage for treatments by licensed CAM providers, or for specific types of CAM, such as acupuncture, differ significantly from proposals to mandate coverage for evidence-based CAM treatments. Covering only evidence-based treatments would make it more likely that related health care spending would be invested effectively. Health care spending is finite, and money spent on CAM is money that

153. California Health Benefits Review Program (CHBRP), *Analysis of Assembly Bill 72: Health Care Coverage: Acupuncture, Report to California State Legislature*, Oakland, CA: CHBRP, 11-03 (2011).

154. California Health Benefits Review Program (CHBRP), *Analysis of Assembly Bill 72: Health Care Coverage: Acupuncture, Report to California State Legislature*, Oakland, CA: CHBRP, 11-03, at 4–5, 8 (2011).

155. The increase to total annual next expenditures was estimated to be 0078%. California Health Benefits Review Program (CHBRP), *Analysis of Assembly Bill 72: Health Care Coverage: Acupuncture*, CHBRP, 11-03, (March 18, 2011), at 7.

156. Federal Acupuncture Coverage Act of 2009, H.R. 646, 111th Cong. (2009).

157. *The Federal Acupuncture Act of 2009 fact sheet*, CONCORD CENTER ACUPUNCTURE, http://www.concordcenteracupuncture.com/forms/hinchey_hr_646_fact_sheet.pdf (last visited Jan. 28, 2012); *H.R. 646: Federal Acupuncture Coverage Act of 2009*, GOVTRACK.US, <http://www.govtrack.us/congress/bill.xpd?bill=h111-646> (last visited Jan. 28, 2012).

might otherwise be spent on allopathic treatments with proven efficacy. If recommendations for reimbursement were to be based on a lower standard of evidence than that required for preventive interventions, it risks investing limited funds on unproven treatments. The vast majority of CAM therapies have not yet been proven safe and effective, and it may be premature to advocate reimbursement of CAM modalities that are yet unproven.

As many CAM treatments have not been rigorously investigated, applying an evidence-based only reimbursement scheme means that consumers will not receive coverage for effective but unstudied treatments. It could be argued that only providing coverage for evidence-based CAM treatments holds CAM to an unreasonable double standard. Most allopathic treatments are not evidence-based yet receive insurance coverage. In fact, some treatments are covered for which significant evidence exists that they are not effective.¹⁵⁸ It is even possible that an independent panel of experts may find no CAM is sufficiently evidence-based to justify a recommendation for reimbursement. While promising evidence exists to support the use of a number of CAM therapies, the evidence may not be at the level of comparable preventive care services recommended by the USPSTF. Therefore, in order to rationally decide which treatments merit insurance coverage, it is critical to improve the quantity and quality of CAM research.

Funding for CAM Research

Most research funding for evaluating allopathic treatments comes from private industry. In 2007, private pharmaceutical and biotech firms spent about \$80 billion to conduct medical research, compared with \$40 billion by government and \$5 billion by foundations.¹⁵⁹ While government spending on CAM research is only a small fraction of that devoted to researching allopathic medicine, private investment in R&D on CAM products and services is negligible.

Most government funding for medical research is provided to NIH. In

158. For example, for patients with osteoarthritis of the knee arthroscopic lavage or debridement are commonly performed despite evidence they have no benefit compared to placebo. Bruce Moseley et al., *A Controlled Trial of Arthroscopic Surgery for Osteoarthritis of the Knee*, 347 *NEW ENG. J MED.* 81 (2002).

159. Adam Keiper, *Medical Research is Dominated by Government and Corporate Funding. How Can Philanthropic Dollars Find a Distinctive Niche?*, *PHILANTHROPY MAGAZINE*, (January 1, 2010), at <http://www.philanthropyroundtable.org/article.asp?article=1617&cat=147>. Some funding is also available from charitable foundations, such as the Bill and Melinda Gates foundation which has provided \$23.91 billion in grants since its inception. *Foundation Fact Sheet*, *BILL & MELINDA GATES FOUNDATION*, <http://www.gatesfoundation.org/about/Pages/foundation-fact-sheet.aspx> (last visited Jan. 28, 2012).

2012, the NIH budget request is \$32 billion. Of this amount, about 83 percent will be used to support community research at universities, medical schools, hospitals and other research facilities, while about 11 percent will support research within NIH.¹⁶⁰ While NCCAM's budget request of \$132 million initially appears large, it is only about 0.4% of the total NIH budget.¹⁶¹ Funding for CAM research has increased in recent years, but it has not kept pace with the large increase in CAM use.

The solution to the lack of public funding for CAM research is greater investment. Larger subsidies for CAM research are warranted given the wide use of CAM by American consumers. The first recommendation of the White House Commission on Complementary and Alternative Medicine Policy was that "Federal agencies should receive increased funding for clinical, basic, and health services research on CAM."¹⁶²

Incentivizing Private Research and Development

It is important to encourage private investment in CAM R&D because most of the money for medical research comes from the private sector.¹⁶³ High levels of private investment for conventional medicines research are necessary in large part because regulatory approval of a new drug requires clinical research that costs hundreds of millions of dollars.¹⁶⁴ Before even allowing a new drug to be used in human trials, the FDA requires evidence that a new drug candidate exhibits pharmacological activity that justifies commercial development and that it will not expose

160. *President's Proposed 2012 NIH Budget*, NATIONAL INSTITUTES OF HEALTH, http://www.nih.gov/about/director/budgetrequest/NIH_BIB_020911.pdf (last visited Jan. 28, 2012).

161. Government funding for CAM is also provided to other centers, such as the National Cancer Institute's Office of Cancer Complementary and Alternative Medicine and the National Library of Medicine. Overall NIH funding for CAM research was 247.6 million in FY 2002. Department of Health and Human Services, Tommy G. Thompson, White House Commission on Complementary and Alternative Medicine Policy, Final Report (March 2002), at 31.

162. *Id.* at 37.

163. The White House Commission recommended "incentives to stimulate private sector investment in CAM research." *Id.* at 143.

164. R&D represents only about fifteen percent of drug company expenses. Frederick M. Abbott & Graham Dukes, *Global Pharmaceutical Policy: Ensuring Medicines for Tomorrow's World*, 28, (Edward Elgar Publishing, 2009). The high cost of drug development is also due to a high failure rate of compounds of potential therapeutic interest. It has been estimated that for every 10,000 compounds screened for biological activity, only 1 will receive FDA approval. The cost of research on failed candidates is included in the estimated cost of new drug approval. The FDA also requires evidence of safety and efficacy for approval of medical devices. *Overview of Device Regulation*, U.S. FOOD AND DRUG ADMINISTRATION, <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/default.htm> (last visited Jan. 28, 2012). Medical procedures are regulated by state legislatures and professional medical organizations through licensure of physicians and other conventional health care providers, and established standards of practice and credentials.

humans to unreasonable risks.¹⁶⁵ To fully approve a drug for U.S. commercialization, a manufacturer must provide the FDA with enough evidence from clinical trials to prove that a drug is safe and effective in its proposed use, and that the benefits of using the drug outweigh the risks.¹⁶⁶

New pharmaceutical drugs have the potential to produce a significant return on investment, even taking into account the level of funding required for development. Pharmaceutical drugs are eligible for patent and other forms of IP protection. Patents permit manufacturers to charge high prices for access to drugs, creating a permissible monopoly over supply. In addition to patent protection, new drug approval results in a period of market exclusivity based on data protection, the so called “new drug product exclusivity” or “Hatch-Waxman exclusivity.”¹⁶⁷ Data-based exclusivity prevents generic drug manufacturers from making use of data submitted in an initial application by an originator pharmaceutical manufacturer for a fixed period of time. In effect, this may extend the exclusivity period for an originator drug beyond the patent term or beyond a finding that a patent is invalid. In applying for regulatory approval of a generic equivalent to an approved on-patent medicine, access to or reliance on the original application for regulatory approval is essential. Being able to access originator data allows generics manufacturers to apply for drug approval without undertaking the costly and time-consuming effort to duplicate clinical tests. Generics manufacturers argue that re-generating clinical test data may be regarded as unethical in that it exposes human subjects to a clinical trial that would add no scientific value, and provides a placebo to some patients in place of a medicine with proven efficacy.

This level of scrutiny is almost never required for CAM products.¹⁶⁸ Nearly all CAM products are regulated as dietary supplements, which under DSHEA are regulated as foods rather than drugs or food additives.¹⁶⁹

165. To approve a drug for testing in humans, the drug’s sponsor must submit an Investigational New Drug (IND) application to the FDA. This application requires information on animal pharmacology and toxicology studies (to assess whether the product is reasonably safe for initial testing in humans), manufacturing information, and clinical protocols and investigator information. *Investigational New Drug [IND] Application*, U.S. FOOD AND DRUG ADMINISTRATION, <http://www.fda.gov/drugs/developmentapprovalprocess/howdrugsaredevelopedandapproved/approvalapplications/investigationalnewdrugindapplication/default.htm> (last visited Jan. 28, 2012).

166. Prior to commercial sale in the U.S., every new drug must be approved in a New Drug Application (NDA) by the FDA. Data gathered during trials of an investigational new drug become part of the NDA. *Id.*

167. New Drug Product Exclusivity is provided by the Federal Food, Drug, and Cosmetic Act under 21 U.S.C. § 505(c)(3)(E)(2011) and 21 U.S.C. § 505(j)(5)(F) (2011).

168. CAM products may be regulated as drugs, medical devices or cosmetics depending in part on their “intended use.” 21 U.S.C. § 312(g)(1)(B) (2011). Intended use is based on claims made by manufacturers or distributors to consumers in advertising, labeling, oral statements, etc. CAM products regulated as dietary supplements have restrictions on the types of claims they are permitted to make.

169. Congress defined the term “dietary supplement” in the Dietary Supplement Health and Education Act

Most dietary supplements are produced, sold and marketed without evidence of safety or efficacy. The FDA bears the burden of proof in any regulatory action against a dietary supplement, and it is the FDA's responsibility to prove a dietary supplement is unsafe before it can be removed from the market.¹⁷⁰

Most CAM products are not patented and do not receive data-based exclusivity. Compared to conventional drugs, CAM products are more similar to commodities in a highly competitive market. CAM does not require private investment for regulatory approval, and without intellectual property protection, the ability of manufacturers to recoup large expenditures for clinical research is limited. Competitors are able to free-ride and equally benefit from the results of research. The challenges associated with protecting the intellectual property content of CAM may slow the rate of innovation and R&D.

Challenges Protecting CAM Intellectual Property

CAM is generally patentable when its products or methods are new, non-obvious and useful. This is the case when CAM is used for bioprospecting, with as much as one-third to one-half of pharmaceutical drugs originally derived from plants.¹⁷¹ Plant-derived pharmaceutical drugs

(DSHEA) of 1994: Dietary supplement "(1) means a product (other than tobacco) intended to supplement the diet that bears or contains one or more of the following dietary ingredients: (A) a vitamin; (B) a mineral; (C) an herb or other botanical; (D) an amino acid; (E) a dietary substance for use by man to supplement the diet by increasing the total dietary intake; or (F) a concentrate, metabolite, constituent, extract, or combination of any ingredient described in clause (A), (B), (C), (D), or (E); (2) means a product that - (A)(i) is intended for ingestion in a form described in section 411(c)(1)(B)(i); or (ii) complies with section 411(c)(1)(B)(ii); (B) is not represented for use as a conventional food or as a sole item of a meal or the diet; and (C) is labeled as a dietary supplement; and (3) does - (A) include an article that is approved as a new drug under section 505, certified as an antibiotic under section 507, or licensed as a biologic under section 351 of the Public Health Service Act (42 U.S.C. 262) and was, prior to such approval, certification, or license, marketed as a dietary supplement or as a food unless the Secretary has issued a regulation, after notice and comment, finding that the article, when used as or in a dietary supplement under the conditions of use and dosages set forth in the labeling for such dietary supplement, is unlawful under section 402(f); and (B) not include - (i) an article that is approved as a new drug under section 505, certified as an antibiotic under section 507, or licensed as a biologic under section 351 of the Public Health Service Act (42 U.S.C. 262), or (ii) an article authorized for investigation as a new drug, antibiotic, or biological for which substantial clinical investigations have been instituted and for which the existence of such investigations has been made public, which was not before such approval, certification, licensing, or authorization marketed as a dietary supplement or as a food unless the Secretary, in the Secretary's discretion, has issued a regulation, after notice and comment, finding that the article would be lawful under this Act. Except for purposes of section 201(g), a dietary supplement shall be deemed to be a food within the meaning of this Act." Dietary Supplement Health and Education Act of 1994, Pub. L. No. 103-417, 108 Stat. 4325, 4326 (1994) (codified in scattered sections of 21 U.S.C.).

170. 21 U.S.C § 342 (1994).

171. As much as one-third to one-half of pharmaceutical drugs was originally derived from plants. B. Barrett et al., *Assessing the risks and benefits of herbal medicine: an overview of scientific evidence*, 5 ALTERN. THER. HEALTH MED. 40 (1999).

are generally used in ways that correlate directly with their traditional use.¹⁷² Whether these compounds are purified naturally-occurring substances, or more frequently are synthesized and possibly modified versions of naturally occurring substances, they are generally eligible for patent protection. However, when a pharmaceutical is made from biological resources used in CAM, but outside of traditional guidelines for use, this ceases to be CAM and becomes conventional medicine. Here CAM simply serves as a resource for new drug development.

It is possible to patent CAM products or methods either as they exist in traditional form or where minor modifications have been made, but barriers exist. The most significant challenge may be the requirement for *novelty* in any new invention. In the U.S., if an invention becomes publically available in any way more than a year before a patent application is filed, the application will be rejected.¹⁷³ Making the invention publically available may include selling the invention, disseminating information about the invention, or documenting the invention in a way that documentation can be accessed by a third party. Because many forms of CAM have been used for generations, disseminated in local communities, and documented in publically available sources, these medicines may fail to qualify for patent protection. The U.S. patent for turmeric, for example, was invalidated when evidence was provided that a traditional use had previously been documented in an ancient Sanskrit text as well as other sources.¹⁷⁴

The requirement for *non-obviousness* is also a significant barrier to patenting CAM. Pharmaceutical drugs derived from natural products involve some form of alteration or purification, and such compounds may be considered a novel and inventive step over naturally-occurring

172. Plant-derived compounds used as drugs are generally used in ways that correlate directly with their traditional uses as plant medicines. Of the 877 small-molecule new chemical entities introduced between 1981 and 2002, roughly half (49%) were natural products, semi-synthetic natural product analogues or synthetic compounds based on natural products. A study investigating plant-derived pure compounds used as drugs identified 122 compounds obtained from 94 species of plants. These compounds are used globally as drugs and 80% are used in ways that correlate directly with their traditional uses as plant medicines by native cultures. See Frank E. Koehn & Guy T. Carter, *The evolving role of natural products in drug discovery*, 4 NATURE REVIEWS DRUG DISCOVERY 206, 206 (2005). A study investigating plant-derived pure compounds used as drugs identified 122 compounds obtained from ninety-four species of plants. These compounds are used globally as drugs and eighty percent are used in ways that correlate directly with their traditional uses as plant medicines by native cultures. Daniel S. Fabricant & Norman R. Farnsworth, *The Value of Plants Used in Traditional Medicine for Drug Discovery*, 109 ENVIRONMENTAL HEALTH PERSPECTIVES 69, 69 (2001).

173. 35 U.S.C. § 102 (2011).

174. Karen Timmermans, *TRIPS, CBD, and Traditional Medicines: Concepts and Questions, Report of an ASEAN Workshop on the TRIPS Agreement and Traditional Medicine*, (Feb. 13-15, 2001), at <http://apps.who.int/medicinedocs/en/d/Jh2996e/6.4.html>.

substances. Because herbal medicines typically comprise natural products in their raw form, it may be difficult to claim that these remedies are *non-obvious* and involve an inventive step. It can also be problematic with CAM to differentiate between *prior art*¹⁷⁵ and a claimed invention, and ascertaining that difference is a prerequisite for assessing inventive step.¹⁷⁶ In addition, patent applications require the identification of inventors, and determining inventorship of CAM may be difficult when it has been developed over generations by an indigenous community.¹⁷⁷

While patents may be possible for some forms of CAM, the consensus from experts in this field has generally been that existing forms of intellectual property are inadequate to protect CAM.¹⁷⁸ Other forms of IP may be used to protect CAM, such as trade secret, copyright and trademark. These forms of IP may help CAM products to be marketed on the basis of “brand” quality and to market proprietary formulations of ingredients. However, such IP protections are generally inadequate to protect medicines because they do not prevent bioequivalent generic versions from entering the market and competing. In the case of dietary supplements, competitors may market the same combination of ingredients, although they may not be bioequivalent (in fact the original supplement may not be well-standardized). Marketing then becomes the primary means of distinguishing a supplement from its competitors, which is not unlike the case of brand name pharmaceuticals once generics enter the market.

In theory, it is possible for CAM products to obtain market exclusivity based on regulatory approval in the same manner as conventional drugs.¹⁷⁹ Under the Hatch-Waxman Act, when a product is

175. Prior art refers to existing body of knowledge against which an invention is judged to determine if it is novel and innovative.

176. See generally Xuan Li & Weiwei Li, *Inadequacy of Patent Regime on Traditional Medicinal Knowledge—A Diagnosis of 13-Year Traditional Medicinal Knowledge Patent Experience in China*, 10(2) J. WORLD INTELL. PROP. 125 (2007).

177. See generally SILKE VON LEWINSKI, *INDIGENOUS HERITAGE AND INTELLECTUAL PROPERTY: GENETIC RESOURCES, TRADITIONAL KNOWLEDGE AND FOLKLORE*, 97–100, (Second Edition 2008).

178. See, e.g., World Intellectual Property Organization (WIPO), *Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore, Third Session*, WIPO/GRTKF/IC/3/7 (May 6, 2002), at 70 (discussing the inadequacy of existing intellectual property regimes to protect Traditional Knowledge); see also Graham Dutfield, *TRIPS-Related Aspects of Traditional Knowledge*, 33 CASE W RES J. INT’L L. 233, 248 (2001).

179. The term drug means: “(A) articles recognized in the official United States Pharmacopoeia, official Homeopathic Pharmacopoeia of the United States, or official National Formulary, or any supplement to any of them; and (B) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; and (C) articles (other than food) intended to affect the structure or any function of the body of man or other animals; and (D) articles intended for use as a component of any articles specified in clause (A), (B), or (C). A food or dietary supplement for which a claim, subject to sections 403(r)(1)(B) and 403(r)(3) [of the Act] or sections 403(r)(1)(B) and (r)(5)(D), is made in

approved by the FDA under a New Drug Application, the product may be eligible for market exclusivity.¹⁸⁰ Products containing new chemical entities¹⁸¹ are eligible for a 5-year period of exclusivity,¹⁸² whereas products involving previously approved chemical entities are eligible for a 3-year period for “new uses.”¹⁸³ Likewise, if a CAM product were approved under an NDA, the approval would be specific to that product, which may then be eligible for market exclusivity. CAM products may qualify as new chemical entities.¹⁸⁴

Recently, the line between conventional drug and CAM-product approval has blurred with the advent of botanicals¹⁸⁵ approved as drugs. In 2004, the FDA eased regulations on herbal mixtures, allowing the approval of substances that have adequate evidence of safety and efficacy even if individual constituents are unknown.¹⁸⁶ In October 2006, the first topical medicine, Veregen™, was approved under these rules.¹⁸⁷ This

accordance with the requirements of section 403(r) is not a drug solely because the label or the labeling contains such a claim. A food, dietary ingredient, or dietary supplement for which a truthful and not misleading statement is made in accordance with section 403(r)(6) is not a drug under clause (C) solely because the label or the labeling contains such a statement.” 21 U.S.C. § 321(g)(1) (2011).

180. New Drug Product Exclusivity is limited to a maximum of either a 5-year extension or a 14-year term from the time of FDA approval.

181. A new chemical entity refers to a drug that contains no active moiety (the molecule or ion responsible for the pharmacological action of the drug substance) previously approved by FDA in any other application submitted under section 505(b) of the Act.

182. In addition, no ANDA (for a generic drug) may be submitted during the 5-year period except if they contain a certification of patent invalidity or noninfringement, in which case they may be submitted after 4 years.

183. For example, changes to the active ingredient(s), strength, dosage form, route of administration or conditions of use. To receive a three year period of marketing exclusivity the NDA must contain reports of new clinical studies essential to approval of the application.

184. A new botanical drug containing multiple chemical constituents may qualify as a NCE under § 314.108(a).

185. As opposed to synthetic, semi-synthetic or otherwise highly purified or chemically modified drugs (including antibiotics derived from microorganisms). Botanicals as defined by the FDA are finished, labeled products that contain plant matter as ingredients. A botanical product may be regulated by the FDA as a dietary supplement, cosmetic, food, drug, or medical device. U.S. FOOD AND DRUG ADMINISTRATION, GUIDANCE FOR INDUSTRY BOTANICAL DRUG PRODUCTS 2 (2004).

186. *See id.* for a discussion of guidance on submitting investigational New Drug Applications for botanical drug products.

187. The FDA has indicated a willingness to approve oral botanical drugs, and several promising candidates are in development. *See id.*, for a discussion of guidance on submitting Investigational New Drug Applications (IND) for botanical drug products. For example, a pharmaceutical company founded in association with Yale University, PhytoCeutica, is developing a unique botanical extract, named “PHY906,” as a broad-spectrum chemotherapy adjuvant. Wing Lam, et al., *The Four-Herb Chinese Medicine PHY906 Reduces Chemotherapy-Induced Gastrointestinal Toxicity*, 2(45) J. SCI. TRANSLATIONAL MED. 1, 1 (2010). This extract is a proprietary preparation of a traditional Chinese herbal formula, “Huang Qin Tang,” which has been used to treat gastrointestinal problems for thousands of years. Ewen Callaway, *How an 1,800-year-old Herbal Mix Heals the Gut*, NATURE NEWS, (Aug. 18, 2010), <http://www.nature.com/news/2010/100818/full/news.2010.417.html> (last visited Jan. 28, 2012). Phase I/II clinical trials have demonstrated PHY906 reduces toxicity of chemotherapy and also enhances the effects of cancer treatment. This compound is currently in Phase II/III clinical trials as a FDA-approved

topical herbal preparation is a purified green tea extract for the treatment of warts.¹⁸⁸ Veregen was supported by extensive clinical research and approved in the standard NDA. This botanical preparation is now approved as a pharmaceutical drug and prescribed by physicians.¹⁸⁹

CAM products may also be approved as over-the-counter (OTC) drugs. OTC drugs do not require a physician's prescription and are bought off-the-shelf. OTC drugs are regulated by the FDA through monographs, which are "recipe books" that include information on acceptable ingredients, doses, formulations, and labeling. Products that conform to a monograph may be marketed without additional FDA approval. Products that do not conform to a monograph must undergo independent review through an NDA, regardless of whether they will ultimately be approved as prescription drugs¹⁹⁰ or for OTC use.¹⁹¹ Whether a CAM product would be approved as a prescription or OTC drug depends on the indications and characteristics of the product, and whether it is safe for use outside the supervision of a health care provider licensed to provide it. If a CAM product is not the subject of an NDA, marketing as an OTC drug does not provide market exclusivity. When a final OTC drug monograph is published for a CAM product, any party may market a product in

investigative new drug.

188. Veregen is also protected under patent. Jayesh Chaudhary, *Botanical Drugs: An Emerging Opportunity for Indian Pharma*, EXPRESS PHARMA, (Nov., 2007), <http://www.expresspharmaonline.com/20071130/cphlindia07.shtml> (last visited Jan. 28, 2012).

189. Botanicals may also be available by prescription as medical foods. A medical food, as defined in section 5(b) of the FDA's 1988 Orphan Drug Act (21 U.S.C. 360ee (b) (3)) is "a food which is formulated to be consumed or administered entirely under the supervision of a physician and which is intended for the specific dietary management of a disease or condition for which distinctive nutritional requirements, based on recognized scientific principles, are established by medical evaluation." 21 U.S.C. § 360ee(b)(3) (2011). Medical foods are neither drugs nor dietary supplements; they are intended to meet distinctive nutritional requirements of a disease or condition and used under medical supervision (i.e., they require a prescription). Medical foods undergo special formulation and processing, they are not foods used in their natural state. Ingredients in medical foods must either be GRAS or approved food additives or food additives that are the subject of an exemption for investigational use. Medical foods must conform to the FDCA's general food and safety labeling requirements, but do not require premarket approval by the FDA and individual products do not have to register with the FDA. Labels for medical foods cannot make drug claims or claim to alleviate symptoms. See *Medical Foods*, ALZHEIMER'S ASSOCIATION, http://www.alz.org/national/documents/statements_medicalfoods.pdf (last visited Jan. 28, 2012). Limbrel™ is an example of a medical food. It consists of flavocoxid, a proprietary blend of botanicals, and zinc bisglycinate and is used to manage osteoarthritis by addressing the dietary imbalances of the metabolic processes involved in joint disease. *Limbrel 500 Patient Brochure*, LIMBREL.COM, www.limbrel.com/pdfs/FAQ_english.pdf (last visited Jan. 28, 2012).

190. Prescription drugs require an individual prescription from a physician or appropriately licensed health care provider and are dispensed at a pharmacy. These medicines are regulated by the FDA through the NDA process, which includes all animal and human data and analysis as well as information about how the drug behaves in the body and how it is manufactured.

191. A manufacturer may also petition to change a final monograph to include additional ingredients or to modify labeling, but this does not grant marketing exclusivity.

conformity with the monograph. The benefit to approval as a drug, whether prescription or OTC, is that it allows manufacturers of CAM products to claim their medicines can prevent disease or be used to diagnose, mitigate, treat, or cure disease.

Unfortunately, most CAM products are not in a position to seek approval in an NDA. Since CAM products can already be marketed as dietary supplements with relatively minimal regulation, most manufacturers have little incentive to generate the necessary clinical data for an NDA. Although dietary supplements are not permitted to make claims to treat or prevent illness, they are permitted to make health claims, include nutrient content, and structure/function claims, which can be similar to claims to treat illness.¹⁹² Manufacturers of CAM products are apparently unwilling to invest in the necessary clinical research to support an NDA in return for three or five years of market exclusivity.

Protecting CAM Under *Sui Generis* Regimes

Difficulties in protecting CAM intellectual property under the existing system have led to proposals to establish a *sui generis* regime. In the context of intellectual property, *sui generis* laws refer to a unique set of protections for a particular subject matter.¹⁹³ For example, The Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) requires that nations provide IP protection for plant varieties, but permits nations to provide either patent protection or *sui generis* protection. In the United States, *sui generis* laws protect the topography of semiconductor chips¹⁹⁴

192. Health claims describe a relationship between a dietary supplement ingredient and reduced risk of a disease condition, nutrient content claims describe the relative amount of a dietary substance in a product, and structure/function claims describe how supplements may affect the organs or systems of the body without mentioning any specific disease. In practice, structure/function claims may promise vaguely worded health benefits that can be similar to claims to treat illness. Examples include “calcium builds strong bones” and “fiber maintains bowel regularity.” FDA approval is not required for structure/function claims, but manufacturers must provide the FDA with the text of the claim within 30 days of product marketing. Claims must be followed by the disclosure that, “This statement has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure or prevent any disease.” *Dietary Supplement Labeling*, FOOD AND DRUG ADMINISTRATION, <http://www.fda.gov/food/labelingnutrition/labelclaims/ucm111447.htm> (last visited Jan. 28, 2012).

193. For analysis of these laws in more detail, see generally World Intellectual Property Organization (WIPO), Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge, and Folklore, Fifth Session, *Consolidated Analysis of the Legal Protection of Traditional Cultural Expressions*, WIPO/GRTKF/IC/5/3 (May 2, 2003).

194. “Semiconductor topography” refers to the electrically-functional design of a silicon chip. Semiconductor products are an essential part of modern electronic equipment and comprise a multi-billion dollar annual market. In the U.S., the Semiconductor Chip Protection Act of 1984 (SCPA) protects the semiconductor topographies upon registration, providing defenses against illegal copying. 17 U.S.C. §§ 901-914 (2011). This Act was an innovative solution to a novel technological problem. Although some principles of patent and copyright law underlie the Act, it is uniquely adapted to semiconductor

and integrated circuits. Several nations have taken the initiative in providing specialized protection for CAM in intellectual property systems. China, for example, has the oldest patent regime for CAM protection.¹⁹⁵ Chinese patent law protects new CAM products, methods of process, and uses of traditional medicine. This includes herbal preparations, extracts from herbal medicines, foods containing herbal medicines, methods for preparing herbal formulas and new medical indications for traditional formulas.¹⁹⁶ The protection of inventions related to CAM in China is effectively integrated with the regular patent system. By 2002, the Chinese State Intellectual Property Office (SIPO) had received 20,864 patent applications related to TCM.¹⁹⁷ These applications are managed by a group of more than 30 CAM-specialist patent examiners. About 4,000 applications a year are now submitted in this field domestically.¹⁹⁸

Internationally, the focus of debate over protection efforts has largely been on traditional knowledge rather than complementary and alternative medicine. In part, this is because traditional knowledge is intimately associated with the rights of indigenous peoples. There has been increased international recognition of these rights, evidenced by the U.N. Declaration on the Rights of Indigenous Peoples.¹⁹⁹ The U.N. Declaration acknowledged an indigenous right to maintain, control, protect and develop traditional knowledge.²⁰⁰ The focus on traditional knowledge may

topographies. Protection is acquired by filing an application with identifying product material to the U.S. Copyright Office for registration. Protection continues for ten years from the date of registration. Worldwide, legislation on semiconductor topography has been harmonized by the TRIPS Agreement. The Semiconductor Chip Protection Act of 1984 is codified at 17 U.S.C. §§ 901-915.

195. Li, *supra* note 176.

196. WHO, *supra* note 68, at 21.

197. Silke, *supra* note 177, at 104.

198. Silke, *supra* note 177, at 124.

199. In September 2007, the UN General Assembly adopted the United Nations Declaration on the Rights of Indigenous Peoples. The Declaration has sections directly relevant to protection of traditional knowledge, although it has no binding legal force on signatories. For example, Art 24 states: "(1). Indigenous peoples have the right to their traditional medicines and to maintain their health practices, including the conservation of their vital medicinal plants, animals and minerals. Indigenous individuals also have the right to access, without any discrimination, to all social and health services. 2. Indigenous individuals have an equal right to the enjoyment of the highest attainable standard of physical and mental health. States shall take the necessary steps with a view to achieving progressively the full realization of this right." United Nations Declaration on the Rights of Indigenous Peoples, G.A. Res. 61/295, at Art. 24, U.N. GAOR, 107th plen. mtg., U.N. Doc. A/RES/61/295 (Sept. 13, 2007), *available at* http://www.un.org/esa/socdev/unpfii/documents/DRIPS_en.pdf.

200. *See id.* at art. 31 ("Indigenous peoples have the right to maintain, control, protect and develop their cultural heritage, traditional knowledge and traditional cultural expressions, as well as the manifestations of their sciences, technologies and cultures, including human and genetic resources, seeds, medicines, knowledge of the properties of fauna and flora, oral traditions, literatures, designs, sports and traditional games and visual and performing arts. They also have the right to maintain, control, protect and develop their intellectual property over such cultural heritage, traditional knowledge, and traditional cultural expressions. . . . In conjunction with indigenous peoples, States shall take effective measures to recognize

also be due to the fact that developing countries, which are the main proponents of an international agreement on traditional knowledge, are rich in this resource and in associated biodiversity. CAM, on the other hand, may refer to traditional knowledge adopted outside of its traditional context or modern practices developed in industrialized nations.

Advocacy for *sui generis* regimes and an international agreement to protect traditional knowledge has become more prominent in recent years. The Convention on Biological Diversity (CBD) is an international treaty adopted in 1992 to promote conservation of biological diversity, sustainable use of natural resources, and fair and equitable benefit sharing arising from use of genetic resources.²⁰¹ It recognizes that States have the sovereign right to control access to and exploitation of domestic biological and genetic resources.²⁰² Article 8(j) is directly relevant to TM. It states that a nation party to the Convention shall, as far as possible and as appropriate, “Subject to its national legislation, respect, preserve and maintain knowledge, innovations and practices of indigenous and local communities embodying traditional lifestyles relevant for the conservation and sustainable use of biological diversity and promote their wider application with the approval and involvement of the holders of such knowledge, innovations and practices and encourage the equitable sharing of the benefits arising from the utilization of such knowledge, innovations and practices.”²⁰³ Currently, 193 nations are parties to the CBD; the United States is not.²⁰⁴

A supplementary agreement to the CBD was adopted in October 2010, the *Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization to the Convention on Biological Diversity*.²⁰⁵ It provides a legal framework for access and benefit sharing (ABS) arising from the use of genetic resources and associated traditional knowledge.²⁰⁶ The Protocol establishes more detailed rules regarding the mechanisms for providing information to national patent offices and other stakeholders, and for sharing benefits on mutually agreed terms. The Protocol has not yet entered into effect.

and protect the exercise of these rights.”).

201. *Convention on Biological Diversity*, 1760 U.N.T.S. 79 (1992), at <http://www.cbd.int/convention/convention.shtml>.

202. *Id.* at art. 3.

203. *Convention on Biological Diversity*, *supra* note 201, at Art. 8(j).

204. *List of Parties*, CBD, <http://www.cbd.int/convention/parties/list/> (last visited Jan. 28, 2012).

205. *Secretariat of the Convention on Biological Diversity, Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization to the Convention on Biological Diversity*, CBD, <http://www.cbd.int/abs/doc/protocol/nagoya-protocol-en.pdf>.

206. *About the Protocol*, CBD, <http://www.cbd.int/abs/about/> (last visited Jan. 28, 2012).

The primary forum for debate over the protection of traditional knowledge is the World Intellectual Property Organization (WIPO). Currently, draft texts of international legal instruments to ensure the effective protection of genetic resources, traditional knowledge and traditional cultural expression are being negotiated. The WIPO Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore (IGC) was established by the WIPO General Assembly in 2000 to study the relationship between intellectual property and these subjects.²⁰⁷

Crafting a Domestic *Sui Generis* Regime

Providing specialized IP protection for CAM is a complex task. To begin, such protection would look considerably different based on the policy objectives of the law being crafted. The current draft of the instrument for protection of traditional knowledge acknowledges a wide variety of policy objectives.²⁰⁸ Indigenous communities holding traditional medical knowledge may not want to commercialize their knowledge if, for example, it is traditionally considered sacred. Developing countries may wish to prevent further incidents of misappropriation of traditional knowledge. This article does not attempt to consider the entire diversity of objectives for protecting traditional medicine and means for achieving those objectives, but rather limits itself to considering the public health benefits of providing IP protections for CAM.

207. *General Assembly Decision, Matters Concerning the Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore*, WIPO, http://www.wipo.int/edocs/mdocs/tk/en/wipo_grtkf_ic_15/wipo_grtkf_ic_15_ref_decision_28.pdf (last visited Jan. 28, 2012).

208. This includes: "(i) Recognize the holistic nature of traditional knowledge, including its social, spiritual, economic, intellectual, educational and cultural importance; (ii) Promote respect for traditional knowledge systems; for the dignity, cultural integrity and intellectual and spiritual values of the traditional knowledge holders who conserve and maintain those systems; (iii) Meet the actual needs of holders of traditional knowledge holders; (iv) Promote conservation and preservation of traditional knowledge; (v) Empower holders of traditional knowledge and acknowledge the distinctive nature of traditional knowledge systems; (vi) Support traditional knowledge systems; (vii) Contribute to safeguarding traditional knowledge; (viii) Repress unfair and inequitable uses of traditional knowledge; (ix) Operate consistently with relevant international agreements and processes; (x) Promote innovation and creativity; (xi) Ensure prior informed consent and exchanges based on mutually agreed terms; (xii) Promote the fair and equitable sharing of benefits arising from the use of traditional knowledge; (xiii) Promote community development and legitimate trading activities; (xiv) Preclude the grant of improper intellectual property rights to unauthorized parties; (xv) Enhance transparency and mutual confidence in relations between traditional knowledge holders on the one hand, and academic, commercial, educational, governmental and other users of traditional knowledge on the other, including by promoting adherence to ethical codes of conduct and the principles of free and prior informed consent; (xvi) Complement protection of traditional cultural expressions." *Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore*, WIPO, http://www.wipo.int/edocs/mdocs/tk/en/wipo_grtkf_ic_17/wipo_grtkf_ic_17_5.pdf.

A *sui generis* regime may have an additional negative non-monetary impact. Because traditional medicines may form a vital part of individual or community identity, human rights issues are intimately bound with CAM. Historically, colonialism and cultural imperialism have marginalized traditional practitioners and medicine, and misappropriation of traditional knowledge has had deleterious effects on community livelihood and cultural identity.²⁰⁹ Stronger IP protections for CAM focused primarily on the public health benefits may fail to adequately address other issues related to CAM. However, *sui generis* laws focused primarily on honoring the rights of indigenous communities and developing nations to traditional knowledge and genetic resources may fail to incentivize private research on CAM.

The key to good intellectual property protection law is striking a balance between encouraging innovation and providing access to new inventions. One of the most significant drawbacks to IP protections for conventional medicines is that they create obstacles to accessing new technologies. The effects of IP on access to affordable knowledge goods has become an internationally prominent topic of controversy particularly since The Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) established minimum requirements for IP protection for all Member States of the World Trade Organization (WTO). The WTO TRIPS Agreement has been subject to criticism for its adverse effect on access to medicines in developing countries, largely based on its mandate of patent protection to pharmaceutical product subject matter, and also because of its rules regarding regulatory data protection. Any *sui generis* laws intended to incentivize CAM R&D should be crafted with the additional goal of limiting restrictions on consumer access.

209. See, e.g., Graham Dutfield, *TRIPS Related Aspects of Traditional Knowledge*, 33 CASE W. RES. J. INT'L L. 233, 248-61 (2001). In September 2007, the UN General Assembly adopted the United Nations Declaration on the Rights of Indigenous Peoples. The Declaration has sections directly relevant to protection of traditional knowledge, although it has no binding legal force on signatories. Art 24 (1). Indigenous peoples have the right to their traditional medicines and to maintain their health practices, including the conservation of their vital medicinal plants, animals and minerals. Indigenous individuals also have the right to access, without any discrimination, to all social and health services. 2. Indigenous individuals have an equal right to the enjoyment of the highest attainable standard of physical and mental health. States shall take the necessary steps with a view to achieving progressively the full realization of this right. Art 31 (1). Indigenous peoples have the right to maintain, control, protect and develop their cultural heritage, traditional knowledge and traditional cultural expressions, as well as the manifestations of their sciences, technologies and cultures, including human and genetic resources, seeds, medicines, knowledge of the properties of fauna and flora, oral traditions, literatures, designs, sports and traditional games and visual and performing arts. They also have the right to maintain, control, protect and develop their intellectual property over such cultural heritage, traditional knowledge, and traditional cultural expressions. 2. In conjunction with indigenous peoples, States shall take effective measures to recognize and protect the exercise of these rights. United Nations Declaration on the Rights of Indigenous Peoples. *Id.*

Legislative Options

In order to permit a larger group of CAM products to qualify for patent protection, *sui generis* laws might provide more lenient requirements for patenting CAM. In the U.S., pharmaceutical patents are granted for “virtually anything that is ‘different’ from what went before.”²¹⁰ As with Chinese patent law, U.S. law could explicitly provide for protection of new CAM products, methods of treatment and uses of CAM. While this may have a modest impact on the patentability of CAM, the bar may already be set fairly low for the kind of innovation necessary to secure a CAM-based patent.²¹¹ Still, such pro-patent standards for CAM might serve to incentivize CAM-based innovations.

A potential mechanism for striking a better balance might be to grant CAM-products alternatives to standard utility patents in the form of “utility models” or “petty patents.”²¹² The term of these quasi-patents could be limited to fewer than 20 years or the rights of the patent holder could be limited, for example, to collecting a royalty from third-party users rather than excluding them from the market. Only over time would it be clear that the lesser incentive provided by these more limited patents would be sufficient to incentivize investment and innovation while still providing public access.

Although pro CAM-based patent laws may facilitate protection of CAM-based innovations, they would still fail to qualify most CAM products for patent protection. Here, a core division emerges between CAM-based innovations and CAM products already in the public domain. While it is simpler to protect CAM-based innovation under the existing patent system, or with minimal modification based on related subject matter legislation, the most important benefit to public health would result

210. Abbott & Dukes, *supra* note 164, at 34.

211. The U.S. Federal Trade Commission came to this conclusion in an extensive study of U.S. patents as a whole. See *To Promote Innovation: The Proper Balance of Competition and Patent Law and Policy*, A Report by the Federal Trade Commission, (Oct. 2003).

212. “A utility model is an exclusive right granted for an invention, which allows the right holder to prevent others from commercially using the protected invention, without his authorization, for a limited period of time. In its basic definition, which may vary from one country (where such protection is available) to another, a utility model is similar to a patent. In fact, utility models are sometimes referred to as ‘petty patents’ or ‘innovation patents.’ The main differences between utility models and patents are the following: The requirements for acquiring a utility model are less stringent than for patents. While the requirement of “novelty” is always to be met, that of “inventive step” or “non-obviousness” may be much lower or absent altogether. In practice, protection for utility models is often sought for innovations of a rather incremental character, which may not meet the patentability criteria. The term of protection for utility models is shorter than for patents and varies from country to country (usually between 7 and 10 years without the possibility of extension or renewal).” *Protecting Innovations by Utility Models*, WIPO, http://www.wipo.int/sme/en/ip_business/utility_models/utility_models.htm.

from research on *existing* CAM products. Most existing CAM is non-novel, of long-standing use, and considered to be in the public domain. However, to permit patent protection for products that largely seem to be in the public domain requires fairly radical changes to the existing system. Antony Taubman, former Director and Head of the Global Intellectual Property Issues Division (including the Traditional Knowledge Division and Life Sciences Program) of WIPO, writes in respect to protecting traditional knowledge through the patent system,

There is also, clearly, no basis for patent protection with a retrospective character, beyond conventional grace period allowances, given the necessarily rigid stipulations against patenting publically disclosed knowledge. Thus for those countries whose policy concerns focus on the protection of cumulative, collective knowledge systems, and protecting knowledge systems of which some elements at least have been publically disclosed in some way, the patent system has had relatively little attraction.²¹³

Recommendations on how the present patent system with its focus on inventorship and novelty could be adapted to CAM require dealing with complexity and contradictions. Because CAM may have been developed inter-generationally, CAM patents might need to dispense with the requirement to identify individual inventors. However, ownership over CAM is already controversial, and intellectual property law has been criticized for facilitating “biopiracy.”²¹⁴ Without the identification of specific inventors, it would be difficult to determine who should have the right to obtain protection. This might facilitate misappropriation and make it more difficult for the “legitimate” holders of traditional knowledge to

213. Silke, *supra* note 177, at 123.

214. Third parties have patented compounds derived from traditional medicines without the consent of knowledge holders and without fair compensation. A prominent example of third party patenting of traditional medical knowledge without the consent of knowledge holders and without fair compensation includes the patenting of turmeric in the United States. Turmeric (*Curcuma longa*) is an herb traditionally used in Ayurvedic medicine. It is applied as an antiseptic for cuts, burns and bruises, taken internally for digestive disorders, and applied topically for skin disorders. In 1995, the U.S. Patent and Trademark Office (USPTO) granted a patent to the University of Mississippi Medical Center for the medicinal use of turmeric. The patent on "Use of Turmeric in Wound Healing," covered "a method of promoting healing of a wound by administering turmeric to a patient afflicted with the wound." The patent application claimed that this was the first use of turmeric for such a purpose. The issuance of this patent generated international controversy, particularly in India, where it was felt that traditional Indian medicine was being misappropriated. The ensuing public outcry prompted the Indian government to request that the patent be revoked on the basis of lack of novelty due to its known traditional use. The Council of Scientific and Industrial Research of India (CSIR) provided scientific literature documenting prior use of turmeric for wound healing, including an ancient Sanskrit text and a paper published in 1953 in the Journal of the Indian Medical Association. Timmermans, *supra* note 174.

maintain uncontested IP rights. According to natural rights theory, indigenous communities deserve protection for intellectual creations to reward their labor and take into account the shared development of ideas. Exemption from inventorship requirements might be limited to cases in which an indigenous community can document traditional use. However, non-community third-parties may already be marketing a CAM product for which protection is sought. Furthermore, the rights to CAM may rest with a sub-group within an indigenous community, such as a particular family group or traditional healers, or even with a national government under some foreign system of legislation.

To permit patenting of existing CAM products, the statutory bar that prevents patent applications more than one year after the first use, sale or disclosure of an invention might be eliminated for CAM products. The statutory timeframe for conventional patent applications incentivizes inventors to diligently reduce an invention to practice and to promote commercialization. It also helps to obtain widespread disclosure of new inventions to the public as soon as possible, and prevents inventors from commercially exploiting the exclusivity of an invention beyond the statutorily authorized period. Eliminating the statutory bar would fail to provide these incentives. Reducing restrictions on patenting would also impede access. There are benefits to having knowledge in the public domain, which serves as a valuable resource for innovation.²¹⁵ Removing knowledge from the public domain may result in increased costs, including the need to pay to access previously free information.

As a political matter, it is unlikely that the U.S. will independently adopt a *sui generis* regime to protect CAM. It is more likely that the U.S. will accede to an international agreement with requirements to protect traditional knowledge. The U.S. was one of the 184 WIPO Member States that agreed by consensus decision to empower the IGC to develop a text to submit to the WIPO General Assembly by 2011. If the U.S. accedes to such an agreement, domestic legislation would still have to be drafted to achieve compliance.

Unconventional Incentives for Unconventional Medicine

Given difficulties inherent in creating a *sui generis* regime for protecting CAM, it makes sense to consider alternatives to the monopoly

215. See Sara Boettiger & Cecilia Chi-Ham, *Defensive Publishing and the Public Domain*, in INTELLECTUAL PROPERTY MANAGEMENT IN HEALTH AND AGRICULTURAL INNOVATION: A HANDBOOK OF BEST PRACTICES, (Anatole Krattiger et al. (eds.), 2009).

of patents as an incentive for private investment. In recent years there has been increased discussion of a “prize” system for new medicines development. Prizes help decouple the rewards for successful R&D investment from the sales of products, and have been particularly debated as a mechanism for incentivizing research on neglected diseases where the market-share for a successful drug may not justify adequate private investment. The U.S. has established a prize voucher system to reward innovation on 16 neglected diseases.²¹⁶ Prizes are awarded for successful registration of new treatments or vaccines for selected diseases, and winners are entitled to accelerated FDA drug assessment and may sell that priority. Patents are also permitted for these prize-winning innovations.

As an incentive for research on existing CAM products, prizes may be a better option than a radical departure from conventional patenting criteria. Prizes could be granted for proving evidence of safety and efficacy of a CAM product for a particular indication. This might be on the basis of FDA approval in a New Drug Application.²¹⁷ One of the major advantages of the prize system is that the production and distribution of prize-winning medicines could be undertaken without extracting additional innovation rent from consumers. Generic producers could be licensed with the innovation and encouraged to compete on price. The key to a prize system is creating a sufficient incentive structure.²¹⁸ Because there is a need for R&D on many CAM products to demonstrate safety and efficacy, a prize system would not need to follow a “first winner takes all” solution. Manufacturers may be more likely to expend their own resources where there is greater likelihood such investment will be rewarded.

Adequately funded prize systems, unfortunately, are politically challenging to establish due to the large upfront costs they entail. Prizes may save taxpayers money if used as an alternative to conventional IP. However, the ultimate cost of patents and market exclusivity to consumers is non-transparent and therefore may be more politically palatable. Medicare and Medicaid may pay many times over the cost of a prize for access to a new medicine that is protected by a patent, but the expense associated with the patent is spread out over years. Prize systems may also increase overall costs if used together with conventional forms of IP. This is the case with the prize voucher system for neglected diseases, which

216. See Tatum Anderson, *New US Voucher Prize System for Neglected Diseases Launches Amid Doubts*, INTELLECTUAL PROPERTY WATCH, (Aug. 6, 2008), at <http://www.ip-watch.org/weblog/2008/08/06/new-us-prize-system-offers-vouchers-for-neglected-disease-treatments-concerns-arise/>.

217. This process is discussed below in the section on marketing exclusivity.

218. Abbott & Dukes, *supra* note 164, at 58.

permits patents for prize-winning innovations. Here, prizes are being used to incentivize specific research and development goals rather than to save on long-term costs. The projected market for therapies directed at neglected diseases is insufficient to independently incentivize adequate R&D.

Together with, or in place of, a prize system, exclusive or quasi-exclusive marketing rights could be used to incentivize CAM research. The FDCA could be amended to permit a new form of exclusivity for evidence-based CAM products modeled after the Orphan Drug Act.

The Orphan Drug Act

The Orphan Drug Act (ODA) was passed in 1983 to facilitate the commercialization of drugs to treat rare diseases, termed *orphan drugs*. ODA created special incentives for drug developers to seek FDA approval for orphan drugs, including seven years of market exclusivity, government grants for drug development, tax credits, and a streamlined approval process.²¹⁹

ODA has been widely acknowledged as successful.²²⁰ Prior to ODA, only 38 drugs were FDA approved to treat rare diseases.²²¹ Since its passage, the FDA has approved more than 350 orphan drugs and granted orphan designations to more than 2,100 compounds.²²² In 2009, revenue from orphan drugs exceeded \$85 billion, and, in contrast to most industry trends, is expected to exceed \$110 billion by 2015.²²³ The number of orphan product designations in the U.S. has more than doubled in the last decade.²²⁴ Market exclusivity in particular has been identified as responsible for incentivizing companies to develop orphan drugs.²²⁵

Despite its success, ODA is also a cautionary tale. Approved orphan

219. 21 U.S.C. § 360aa-ee (2006). Under the ODA, drugs qualify for orphan status if they are intended to treat a disease affecting fewer than 200,000 American citizens. *Id.*

220. U.S. DEPT OF HEALTH & HUMAN SERVICES, OFFICE OF INSPECTOR GENERAL, 09-00-00380, THE ORPHAN DRUG ACT: IMPLEMENTATION AND IMPACT (2001), available at <http://oig.hhs.gov/oci/reports/oci-09-00-00380.pdf>.

221. Walter Armstrong, *Pharma's Orphans*, PHARMEXEC.com (May 1, 2010), <http://pharmexec.findpharma.com/pharmexec/article/articleDetail.jsp?id=670568>.

222. Benjamin Conway, *Big Pharma Reassesses Orphan Drug Sector*, GEN (May 1, 2010), <http://www.genengnews.com/gen-articles/big-pharma-reassesses-orphan-drug-sector/3202/>.

223. K. Srinivas Sashidhar, *The Rise of Orphan Drugs*, FROST & SULLIVAN (Aug. 2, 2011), <http://www.frost.com/prod/servlet/market-insight-top.pag?docid=239339253>.

224. Press Release, Tufts Center for the Study of Drug Development, U.S. Orphan Product Designations More than Doubled During the Last Decade, According to Tufts Center for the Study of Drug Development (Jan. 20, 2011) (available at http://csdd.tufts.edu/files/uploads/jan-feb_ir_pr.pdf).

225. Patricia Illingworth and Jillian Cohen *Orphan Drug Policies: Implications for the United States, Canada, and Developing Countries* 12 HEALTH L.J. 183 (2004).

drugs come at a high price, as they are free of price controls and generic competition with essentially guaranteed reimbursement. The company Genzyme, for example, charges hundreds of thousands of dollars annually for its enzyme replacement therapies for lysosomal storage diseases.²²⁶ It charges \$200,000 to \$600,000 a year for the drug Cerazyme for the treatment of Gaucher disease.²²⁷ The drug, which patients must take for life, generates more than a billion dollars in revenue annually—the industry definition of a blockbuster.²²⁸

Beyond charging consumers and the government high costs for drugs approved under ODA, some companies have been criticized for taking advantage of the Act to reap large windfalls. Certain drugs developed under orphan status, such as Botox, have gone on to enjoy widespread use for new indications.²²⁹ The FDA cannot rescind orphan drug status in the event a drug turns out to be highly profitable.²³⁰

The colchicine case also demonstrates problems with implementation of ODA. Colchicine has been available in the U.S. as a prescription drug for treating gout since the 19th century.²³¹ In fact, the plant from which colchicine is derived was used as a therapeutic agent for gout more than 3000 years ago in ancient Greece.²³² Despite its long history, colchicine was never approved by the FDA. It was grandfathered into use after the passage of the FDCA, and never officially evaluated by the FDA due to a lack of concern over safety issues.²³³

In July 2009, the FDA approved Colcrys, a brand-name version of colchicine, for treatment of acute gout.²³⁴ URL Pharma, the manufacturer of Colcrys, had conducted studies of Colcrys in healthy volunteers, and conducted a relatively small, randomized, controlled trial of Colcrys in patients with acute gout.²³⁵ Because FDA approval of Colcrys was a new

226. Geeta Anand, *As Costs Rise, New Medicines Face Pushback*, WALL ST. J., Sept. 18, 2007, <http://online.wsj.com/article/SB119007210553130427.html>.

227. Conway, *supra* note 227.

228. *Id.*

229. Jessica Wapner, *Adoption Agents: Keeping Interest in Orphan Drugs Alive*, SCI. AM., June 2, 2010, <http://www.scientificamerican.com/article.cfm?id=adoption-agents&page=2>.

230. Fred Schulte and Doug Donovan, *Drugs earning millions despite 'orphan' label*, BALT. SUN, Dec. 18, 2007, <http://www.baltimoresun.com/news/nation-world/bal-te.orphan18dec18,0,7085040.story>.

231. Aaron S. Kesselheim and Daniel H. Solomon, *Incentives for Drug Development — The Curious Case of Colchicine*, 362 NEW ENG. J. MED. 2045 (2010).

232. *Id.*

233. *Id.*

234. URL PHARMA, *Colcrys vs. Unapproved Colchicine*, http://www.urlpharma.com/url_unapproved_drug_Colcrys.aspx.

235. RA Terkeltaub et al., *High versus low dosing of oral colchicine for early acute gout flare: twenty-four-hour outcome of the first multicenter, randomized, double-blind, placebo-controlled, parallel-group*,

indication for the drug, the manufacturer received three years of market exclusivity under the Hatch-Waxman Act. URL Pharma also received 7 years of market exclusivity for Colcris in the treatment of familial Mediterranean fever (FMF), a genetic disorder affecting about 100,000 people worldwide. The efficacy of colchicine in the treatment of FMF was already established; the orphan indication was approved on the basis of a review of previously collected data together with additional safety information from the Colcris studies.

After approval, URL Pharma filed to remove generic versions of colchicine from the market.²³⁶ It also raised the price of colchicine from \$0.09 per pill to \$4.85 per pill.²³⁷

In the case of colchicine, incentives offered by the Hatch-Waxman Act and ODA successfully encouraged drug research, but the rewards outweighed the value of the information produced.²³⁸ The FDA or NIH could have directly funded trials to address outstanding questions related to colchicine at substantially reduced price and with less potential bias. As a result of Colcris' approval, the public ultimately bore considerable costs—an estimated additional \$50 million annually for state Medicare programs.²³⁹

Perceived abuses of ODA, which was originally intended to produce only modest returns on investment, have even sparked criticism from the Act's co-author, Representative Waxman.²⁴⁰ Related concerns have led the EU to alter the European equivalent of ODA to allow regulators to shorten a drug's market exclusivity if its profits from non-orphan indications are too high.²⁴¹ In 1990, Congress approved similar amendments to ODA that were subsequently vetoed by President George H.W. Bush.²⁴²

dose-comparison colchicine study, 62 *Arthritis & Rheumatism* 1060 (2010).

236. *Mutual Pharmaceutical Co. v. Watson Pharmaceuticals*, 2009 WL 3401117 (C.D. Cal. Oct. 19, 2009).

237. Kesselheim, *supra* note 231; Allan Brett, *Spotlight on Colchicine: The Colcris Controversy*, J. WATCH GENERAL MEDICINE, June 10, 2010, <http://general-medicine.jwatch.org/cgi/content/full/2010/610/1>. (“The controversy enters the picture here: URL Pharma has been given market exclusivity for 3 years, and companies that produce ‘nonapproved’ colchicine — the products that we’ve prescribed for decades — are required to phase out production in 2010. Patients will experience this transition as an extraordinary increase in the cost of the drug: Colcris sells for US\$5 per pill, whereas nonapproved colchicine costs pennies per pill.”).

238. Terkeltaub, *supra* note 235.

239. Kesselheim, *supra* note 231.

240. Geeta Anand, *How Drugs for Rare Diseases Became Lifeline for Companies*, WALL ST. J., Nov. 5, 2015, http://online.wsj.com/public/article/0,,SB113202332063297223-ztfi1Ms5q2Cw_YKhwxKTHN3Tk9g_20051128,00.html?mod=blogs.

241. Armstrong, *supra* note 221.

242. Wapner, *supra* note 229.

Market Exclusivity for Evidence-Based CAM Products

An FDCA amendment to create stronger incentives for drug developers to seek FDA approval of CAM products in an NDA could establish seven years of market exclusivity, government grants for drug development, tax credits and a streamlined approval process. As with a prize system, the key to a successful market exclusivity regime is creating a sufficient incentive structure. A greater value of incentives should result in more approved compounds. This must be balanced against the cost to consumers and the government. There is no magic formula for determining the precise combination of incentives, or a particular time period of exclusivity, needed to stimulate R&D.

Given the success of ODA, it makes sense to design future incentive structures after this proven model. Experience with ODA suggests that increasing government subsidies for CAM research and creating incentives for private sector CAM R&D would successfully improve the evidence-base for CAM and help commercialize new FDA-approved products. At the same time, to prevent unfair pricing, it suggests the need for cost control through anti-trust legislation or compulsory licensing.

Currently, drug developers have the option to seek CAM product approval in an NDA and to receive 3 to 5 years of market exclusivity, even if that product would otherwise qualify for approval as a dietary supplement or OTC drug. However, the lack of CAM products approved in an NDA suggests this has not adequately incentivized R&D on CAM products. It is unclear why this is the case. As stated previously, it may be due to a perception that the cost of clinical trials will outweigh the benefits of limited market exclusivity. Developers may be hesitant to seek FDA approval in an NDA because of institutional resistance to investigating these medicines due to professional stigma or because researchers lack expertise in this area. It may also be due to the existing authority to market CAM products as dietary supplements without costly trials, the belief that FDA approval in an NDA will be more challenging for CAM products, or the genuine challenges inherent in scientifically evaluating CAM products. While there are no guarantees, a market exclusivity regime for evidence-based CAM products modeled after ODA should help to overcome these barriers.

The balance could be shifted to further incentivize New Drug Applications by requiring health insurance reimbursement for CAM products approved in an NDA. Currently, even when a product is prescribed “on-label” for its FDA approved indication, health insurance providers are not required to provide reimbursement. In the case of

Medicare and Medicaid, the Centers for Medicare and Medicaid (CMS) determine product reimbursement independent from FDA approval. In addition, CMS uses a non-uniform regional reimbursement policy that enables Medicare contractors to selectively reimburse for FDA-approved products.²⁴³ Thus, even if a CAM product were approved in an NDA, there is no guarantee insurance companies would reimburse policyholders for its use. If insurance reimbursement were mandated, it would provide an incentive for NDA approval.²⁴⁴ Market protection could be ensured through competition (anti-trust) legislation,²⁴⁵ or a government fund for the “buyout” of CAM products to license the product for use by generics producers. However, insurance companies are likely to oppose mandated reimbursement due to concerns that it may result in increased expenditures. Subsidization from the federal government would help lessen opposition.

This proposed legislation requires a clear definition of what products would qualify for evidence-based CAM product approval (CAM drugs). However, this presents a challenge given the difficulties inherent in defining CAM. The best option may be for eligible candidates to be defined as products that qualify for marketing approval as dietary supplements.²⁴⁶ This would include products without significant safety concerns and exclude products required to go through the standard FDA approval process to reach the market as either prescription drugs or OTC drugs. Dietary supplements will also benefit from FDA approval in an NDA because it permits claims to diagnose, treat, cure, or prevent illness. While the vast majority of dietary supplements are CAM products, the two

243. Gerald Doros, Editorial, *FDA Approval Does Not Mean What You Think It Does!* 22(8) J. INVASIVE CARDIOLOGY 382 (2010).

244. See *id.* (“For a product to be widely employed, reimbursement is mandatory.”).

245. Competition law attempts to preserve an effective competitive framework that promotes the best quality of goods and services at the lowest cost for consumers, ensures the suppliers’ freedom of access to the market and the demands associated with freedom of choice.

246. Alternately, a market exclusivity regime might focus more narrowly on traditional medicines. Traditional medicines are more likely to be safe and effective than modern CAM therapies on the basis of longstanding use. The European Medicines Agency states that in the case of traditional medicines, “the long tradition makes it possible to suppress the need for clinical data, in so far as the efficacy of the medicinal product is plausible on the basis of its long-standing use and experience as testified by bibliographic or expert evidence.” Specific Directive (2004/24/EC) amending, as regards traditional herbal medicinal products, Directive 2001/83/EC on the community code relating to medicinal products for human use, 2004 O.J. (L 136) p. 85-90, Preamble paragraph (5). The EMA is the E.U. equivalent of the FDA. It is the agency that coordinates the evaluation and supervision of medicinal products throughout the EU. European Cancer Coalition, About the European Medicines Agency, <http://www.ecpc-online.org/health-in-eu/emea.html> (last visited Jan. 28, 2012). To focus on traditional medicines, qualification criteria might borrow from those used by the EMA for its traditional use approval. The EMA requires a supplement to possess documentation that it has been used for a period of at least 30 years, including at least 15 years in the EU.

terms are not synonymous. Some mainstream allopathic products are marketed as dietary supplements, for example, vitamins to prevent and treat disease caused by illness, pregnancy, poor nutrition, and digestive disorders. Compared to other allopathic treatments, these dietary supplements are among the least invasive and expensive, and are generally focused on prevention and wellness.

Consumer Protection Statutes

Although administrative regulation of CAM products by the FDA may be lacking,²⁴⁷ other agencies share the task of consumer protection in the field of health care. The Federal Trade Commission (FTC) administers a wide variety of consumer protection laws and adopts industry-wide trade regulations. It has taken action against numerous medical device and dietary supplement manufacturers for deceptive and misleading advertising, and for violations of consumer protection statutes, such as the FTC Act. For instance, in August 2008, the FTC settled with Airborne Health Inc., the manufacturer of the popular dietary supplement Airborne®, for deceptive advertising claims.²⁴⁸ Other recent FTC actions against dietary supplement manufacturers have involved false claims about weight loss and the ability to cure cancer.²⁴⁹ These actions, however, are the exception rather than the rule. As much as consumers may expect regulatory agencies to police the entire health care market, they cannot be expected to do so given shifting political priorities and limited resources.²⁵⁰

247. Peter Barton Hutt, former FDA Chief Counsel, has written that DSHEA has always provided the FDA with the legal authority to prohibit all unsafe or mislabeled dietary supplements in the marketplace, and that it only failed to do so as a result of an order from former Commissioner David Kessler. "Kessler was so infuriated by the enactment of DSHEA, however, that he ordered FDA not to enforce the new law. Initially, this was not widely understood. As time has gone on, however, former FDA enforcement officials have admitted that, for the first full decade under DSHEA, FDA took virtually no enforcement action because of Kessler's policy. Kessler was convinced that, if the law was not enforced and the worst elements of the dietary supplement industry were allowed to run wild, Congress would repeal the law." Peter Barton Hutt, *The History & Future of the Dietary Supplement Health and Education Act*, NATURAL PRODUCTS INSIDER, (Sept. 21, 2009), at <http://www.naturalproductsinsider.com/articles/2009/09/the-history-future-of-the-dietary-supplement-health-education-act.aspx>.

248. The FTC alleged that Airborne Health had no credible evidence to support claims that Airborne prevents colds, protects against airborne illness or reduces cold severity. Airborne Health had already agreed to pay \$23.51 million in consumer refunds and attorney's fees in an earlier class action lawsuit, and the FTC order called for an additional \$6.5 million in refunds if the class action pool did not fully satisfy the consumer refunds. *See Makers of Airborne Settle FTC Charges of Deceptive Advertising; Agreement Brings Total Settlement of Funds to \$ 30 Million*, FTC, <http://www.ftc.gov/opa/2008/08/airborne.shtm> (last visited Jan. 28, 2012). Following the FTC settlement with Airborne, Walgreen's settled a \$1.4 million class action suit over their generic version of the Airborne dietary supplement, Wal-Born®. John B. Reiss et al., *Your Business in Court*, 64(4) FOOD DRUG L.J. 755, 768 (2008-2009).

249. John B. Reiss et al., *Your Business in Court*, 64(4) FOOD DRUG L.J. 755, 765-67 (2008-2009).

250. Former FDA commissioner, David Kessler, stated "[t]he reality is the FDA does not have the resources to perform the Herculean task of monitoring comprehensively the performance of every drug on

Consumer Protection through Tort Liability

Tort liability also plays an important role in providing consumer protection.²⁵¹ Consumers may take legal action in civil court against health care agents including medical providers, pharmaceutical manufacturers, and hospitals, on grounds ranging from medical malpractice to the sale of dangerous products. Civil litigation may help injured parties obtain a measure of justice, and may promote the common welfare by disseminating information to the public. Litigation over pharmaceuticals has led to the withdrawal of drugs that cause more harm than good.²⁵² Product liability law, which functions to provide compensation to injured parties, may provide more deterrence than criminal law against corporate crime in the pharmaceutical industry.²⁵³ On the other hand, if drug profits substantially outweigh the costs of litigation, companies may simply regard litigation costs as a sensible business expense.²⁵⁴ Awards and settlements provide a useful deterrent only if they affect company finances in a meaningful way.

Ideally, civil litigation should complement government regulation.²⁵⁵ Congress did not intend the FDA to be the exclusive means of ensuring drug safety and effectiveness, and as the role of the FDA in medicine regulation has consistently expanded, Congress has taken care to preserve state law.²⁵⁶ In *Wyeth v. Levine*, the Supreme Court ruled that the FDA's drug-labeling decisions did not preempt state law product liability claims. In that case, a Vermont jury found that the drug manufacturer Wyeth had failed to provide an adequate warning on its labeling materials for the drug

the market ... [it is unable] to police drug safety effectively on its own." See Reiss, *supra* note 248, at 756.

251. It is not the intent of the FDA to influence civil tort liability of the manufacturer. Content and Format for Labeling Human Prescription Drugs, 44 Fed. Reg. 37,437 (June 26, 1979). Government regulations and civil suits are not the only mechanisms for consumer protection, consumer organizations and the media also play an important role. In addition, regulatory agencies may initiate criminal proceedings and administrative sanctions.

252. For example, Merck, the maker of Vioxx™, had known its drug caused increased risk of heart attack before alerting the FDA to the risk. During litigation, internal company memos came to light that showed Merck was aware of these risks. Abbott & Dukes, *supra* note 164, at 207.

253. JOHN BRAITHWAITE, CORPORATE CRIME IN THE PHARMACEUTICAL INDUSTRY 246 (Routledge & Kegan Paul Books Ltd., 1984).

254. For example, Eli Lilly Company announced a \$700 million settlement over claims that the drug Zyprexa™ caused diabetes and that the company failed to adequately warn about this adverse effect. However, the following year sales of Zyprexa were \$4.4 billion. Abbott & Dukes, *supra* note 164, at 194.

255. *Wyeth v. Levine*, 555 U.S. 555, fn.10 (2009) ("The FDA regards state law as complementing the agency's mission of consumer protection.")

256. Amendments to the FDCA in 1962 included a saving clause, indicating that a provision of state law would only be invalidated if it was in direct conflict with the FDCA. 21 U.S.C.S. § 301 et seq. (2011). An express pre-emption provision for medical devices in 1976 failed to include a provision for prescription drugs. 21 U.S.C.S. § 360k(a) (2011).

Phenergan®. Labeling was found to be defective despite the fact that the FDA had approved Wyeth's labeling materials. The Court noted that manufacturers bear ultimate responsibility for the content of their labels,²⁵⁷ and that they have a responsibility to update labeling with new safety information based on post-marketing surveillance.²⁵⁸

Several legal theories support a cause of action for medicines-related personal injury. Plaintiffs may allege that a product was defectively manufactured or that there was a failure to warn consumers of associated dangers. A lawsuit may also be brought for fraud-based claims, such as fraudulent misrepresentation, or for negligence or negligent misrepresentation. In addition, there are express and implied warranty claims as well as statutory causes of action relating to unfair and deceptive trade practices. In the case of *Wyeth*, Levine brought an action for damages relying on common law negligence and strict liability theories. Whether strict liability should apply in such cases is controversial. Where it is adopted, liability will be established if damage and proximate cause alone are demonstrated, unless an affirmative defense exists.²⁵⁹

Claims may be brought against dietary supplement manufacturers under the same legal theories.²⁶⁰ The Ephedra controversy, which resulted in the withdrawal of Ephedra from the market, also generated a substantial number of civil lawsuits against Ephedra manufacturers. One class action lawsuit in California against Cytodyne Technologies, the makers of the Ephedra-based product Xenadrine®, resulted in an order for Cytodyne to deposit \$12.5 million in a pool for distribution among plaintiffs.²⁶¹ This amount represented the entirety of profits made by the company in California on Xenadrine. In ruling for the plaintiffs, the judge in that case found that Cytodyne's advertising misstated scientific findings.²⁶²

257. Specific Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products, 21 C.F.R. § 201.80(e) (2011).

258. See 21 C.F.R. § 314.80(b) (2011); Supplemental Applications Proposing Labeling Changes for Approved Drugs, Biologics, and Medical Devices, 73 Fed. Reg. 49,603, 49,605 (August 22, 2008) (to be codified at 21 C.F.R. pt. 314).

259. Defenses may be provided for in relevant product liability law, for example.

260. The most common type of claim brought against a pharmaceutical manufacturer relates to drug injury. Abbott and Dukes, *supra* note 164, at 197. For example, the Merrell Company was sued some 500 times from 1961 onwards due to injuries attributed to the cholesterol-lowering drug triparanol (MER-29™). Although settlements reached with plaintiffs were estimated to have totaled about \$200 million, the manufacturer had anticipated annual sales of the drug amounting to \$4.25 billion. P. KNIGHTLEY ET AL., (1979), *SUFFER THE CHILDREN: THE STORY OF THALIDOMIDE* 65 (Viking Press, 1979). There was also a criminal case brought by the FDA.

261. F. Fessenden, *Judge Orders Ephedra Maker to Pay Back \$12.5 million*, N.Y. TIMES, (May 31, 2003), at 2.

262. For example, one of the company's claims advertised that product users had a 3,860 percent greater fat loss than non-users. This was based on a small company-financed study finding that users lost 1.93

In drug injury cases, an important consideration is whether manufacturers have acted ethically. For example, Metabolife International Inc., the manufacturer of the most popular Ephedra-based weight loss supplement, told regulators in 1998 and again in 1999 that it had never received a consumer report of a serious health problem.²⁶³ The company, meanwhile, had more than \$350 million in revenue and a profit of \$24 million in 1999.²⁶⁴ In 2002, under pressure from the FDA and the Justice Department, Metabolife International admitted it had actually received approximately 13,000 consumer complaints of adverse health effects.²⁶⁵ The company was subsequently sued in numerous civil suits and settled more than 400 personal injury claims before a “litigation onslaught” forced it to file for Chapter 11 bankruptcy in June 2005.²⁶⁶

The FDA has experienced several notable regulatory policy failures over the past several years, and studies by the Government Accountability Office (GAO) and IOM have been critical of the agency’s ability to keep unsafe drugs off the market and to respond effectively to unforeseen hazards with newly approved drugs.²⁶⁷ The FDA has also experienced

percent of their body fat compared to 0.05 by non-users.

263. Penni Crabtree, ‘*Litigation Onslaught*’ Threatens Maker of Banished Ephedra Pill, SAN DIEGO UNION TRIBUNE, (January 5, 2005), at http://www.metabolife-356.com/metabolife_seeks_settlement.html.

264. *Id.*

265. Crabtree, *supra* note 263.

266. *Id.* At that time, hundreds of personal injury claims were pending against the company seeking more than \$1 billion in damages. *Metabolife Attempting Settlement of Ephedra Claims*, NATIONAL LEGAL NEWS, (June 1, 2006), at <http://www.frg-law.com/lawyer-attorney-1384718.html>. These claims finally settled in a bankruptcy proceeding as a \$56 million global settlement benefiting tort claimant creditors. *Brown Rudnick Reaches Settlement in Metabolife Suit*, BOSTON BUSINESS JOURNAL, (Nov. 13, 2006), at <http://www.bizjournals.com/boston/stories/2006/11/13/daily14.html>. The company and its owners also faced civil and criminal liability for embezzlement, filing fraudulent tax returns, and for making false statements to the FDA. The company and its former chief executive, Michael Ellis, were indicted on eight counts of making false statements to the FDA in an effort to obstruct regulation of *Ephedra*. Ellis ultimately pled guilty to a single count of lying to the FDA and was sentenced to 6 months in federal prison and a \$20,000 fine. Mike Allen, *Metabolife Founder gets 6-month Prison Sentence*, SAN DIEGO BUSINESS JOURNAL (June 10, 2008). William Bradley, one of Metabolife’s three owners, pled guilty to filing fraudulent tax returns and was sentenced to 6 months in federal prison and a criminal fine of \$600,000. United States Department of Justice, Office of the US Attorney Southern District of California, News Release, *Metabolife and Owner William Bradley Plead Guilty to Tax Charges*, (Oct. 5, 2005), at http://www.justice.gov/tax/usaopress/2005/txdv05cas51005_1.pdf (last visited Jan. 28, 2012). See also Matt Potter, *Breaking Stories: Case Closed*, SANDIEGOREADER.COM, <http://www.sandiegoreader.com/news/2006/oct/05/case-closed/> (last visited Jan. 28, 2012). Companies may prefer to settle cases rather than have such information become public knowledge through trial.

267. *Risk and Responsibility: The Roles of the FDA and Pharmaceutical Companies in Ensuring Safety of Approved Drugs, Like Vioxx. Hearing before the H. Comm. On Government Reform*. 109th Cong. 23, 55 (2005) (testimony of Steven Galson, Acting Director, Center for Drug Evaluation and Research, FDA); COMMITTEE ON THE ASSESSMENT OF THE US DRUG SAFETY SYSTEM, *THE FUTURE OF DRUG SAFETY—PROMOTING AND PROTECTING THE HEALTH OF THE PUBLIC*, 153-4, (Alina Baciu et al., eds.) (National Academies Press, 2007).

major problems in the regulation of manufacturing practices, as witnessed by the difficulties with heparin imports from China. In that case, the FDA failed to adequately monitor the Chinese production chain.²⁶⁸ The ability of the FDA to gather post-marketing data is ineffective compared to that of industry, and internal industry materials related to drug risks may only come to light during tort litigation. Therefore, in drawing conclusions about the wisdom of more stringent regulation of dietary supplements, one should not assume that additional regulation is a panacea. As a practical matter, a large part of consumer protection is a matter of self-policing and company reputation.

Consumer Protection and CAM Services

CAM services are informally regulated through a variety of mechanisms including provider licensing and credentialing, professional discipline, malpractice liability, and health care fraud.²⁶⁹ Although physicians are able to provide CAM services as part of their “unlimited” scope of practice, by doing so they risk added malpractice liability and discipline by state medical boards.²⁷⁰ Malpractice claims require that physician practice falls below the standard of care, generally defined as the degree of care, skill and learning ordinarily applied by other members of the profession,²⁷¹ and because most CAM treatments are unconventional, courts may view the absence of mainstream medical acceptance or FDA approval as evidence that a doctor has failed to follow the standard of

268. FDA’s Ongoing Heparin Investigation: Statement of Janet Woodcock, Director, Center for Drug Evaluation and Research before the Subcommittee on Oversight and Investigations House Committee on Energy and Commerce, at <http://www.fda.gov/NewsEvents/Testimony/ucm115242.htm>.

269. The provision of CAM services is also dependent on institutional policies, patient access to treatment and third-party reimbursement.

270. This applies to other conventional licensed health care providers such as nurses and physical therapists. In addition, some states have requirements for physician training and credentialing, for example California requires physicians to have 300 hours of training to provide acupuncture. Michael H. Cohen, *Legal and ethical issues in complementary medicine: a U.S. perspective*, 181(3) MED. J. AUSTRAL. 168 (2004). The North Carolina state medical board revoked a physician’s license to practice medicine for practicing homeopathy in the absence of patient injury. Although this decision was overturned in superior court and appellate court, the North Carolina Supreme Court upheld the medical board’s decision based on the statutory definition of professional misconduct. Misconduct was defined as any departure from “acceptable and prevailing” practice. *In re Guess*, 393 S.E.2d 833 (N.C. 1990), cert. denied *Guess v. North Carolina Bd. of Medical Examiners*, 498 U.S. 1047 (1991), later proceeding *Guess v. Board of Medical Examiners*, 987 F.2d 998 (4th Cir. 1992).

271. The definition of standard of care may vary by jurisdiction. In Ohio, for example, “The standard of care for a physician or surgeon in the practice of a board-certified medical or surgical specialty should be that of a reasonable specialist practicing medicine or surgery in that same specialty in the light of present day scientific knowledge in that specialty field; therefore, geographical considerations or circumstances control neither the standard of the specialist’s care nor the competence of the testimony of an expert in that specialty.” *Bruni v. Tatsumi*, 46 Ohio St. 2d 127 (1976).

care.²⁷² In addition, physicians practicing in hospitals or other institutions may be constrained in terms of what types of services they can provide. For example, a hospital may prohibit even appropriately trained and certified physicians from practicing acupuncture due to concerns over liability.²⁷³

CAM providers, like physicians, are regulated by states as part of their constitutional mandate to regulate health, safety, and welfare. Unlike physicians, however, CAM providers have a relatively limited scope of practice, and provider regulation varies greatly by state.²⁷⁴ For example, chiropractors are licensed in all states with variable restrictions on scope of practice.²⁷⁵ Other forms of CAM such as hypnotherapy, energy healing and mind-body practices generally lack regulation.²⁷⁶ In the case of acupuncture, 43 states and the District of Columbia regulate non-physician practice.²⁷⁷ In general, acupuncture licensure requires 3 years or 1,800

272. The “respectable minority” or “two-minds” doctrine may provide a defense to claims that CAM treatments fail to follow the standard of care. The doctrine permits a different standard of care than that endorsed by the majority of physicians where it is practiced by a respectable number of physicians. What constitutes a respectable number of physicians is not well defined. “Assumption of risk” may also provide a defense to malpractice where a patient has expressly accepted something other than the mainstream standard of care and has agreed to assume any ensuing risks.

273. Mere referral to a CAM provider does not generate malpractice liability for subsequent negligence by that provider. Michael H. Cohen & David M. Eisenberg, *Potential Physician Malpractice Liability Associated with Complementary/Integrative Medical Therapies*, 136 ANN INTERN MED 596 (2002); DM Studdert et al., *Medical Malpractice Implications of Alternative Medicine*, 280 JAMA 1610 (1998). Exceptions to this rule exist where joint treatment is undertaken, when referral delays necessary treatment resulting in harm, or when referral is made to a provider the physician knew or should have known might be incompetent. Institutional providers such as hospitals may also risk added liability by providing CAM services. Direct liability may be imposed on institutions for failing to properly supervise health care providers, and vicarious liability for a CAM provider who acts negligently.

274. For example, in some states naturopathic physicians can prescribe certain prescription drugs and licensed acupuncturists can recommend traditional herbal medicines. Unlicensed CAM providers are legally permitted to practice under certain conditions with strict limitations on the care they are permitted to provide. Michael H. Cohen, *Legal and Ethical Issues in Complementary Medicine: A U.S. Perspective*, 181(3) MED. J. AUSTL. 168 (2004). Laws in California, Minnesota, and Rhode Island, for example, permit non-licensed health care providers to offer a range of CAM therapies, so long as they make appropriate disclosures to health care consumers and meet other requirements. Michael H. Cohen, *Regulating ‘Healing:’ Notes on the Ecology of Awareness and the Awareness of Ecology*, 78(4) ST. JOHN’S L. REV. 1167, 1186 (2005). For example, Minnesota has model legislation for the practice of CAM and non-licensed CAM practitioners such as homeopaths are recognized and governed by statute. Homeopaths have a duty to inform patients of their rights under Minnesota law through a written form and prominent displays of information including the practitioner’s degree of training and disclosure of the state’s lack of educational standard. Homeopaths licensed by another state board are governed by that board. Anna M. Richardson, Student Article, *Informed Patients go Homeo Happy: Applying the Doctrine of Informed Consent to Homeopathic Practitioners*, 34 OHIO N.U.L. REV. 593, 598–9 (2008).

275. *Id.*

276. *Credentialing CAM Providers: Understanding CAM Education, Training, Regulation and Licensing*, NATIONAL CENTER FOR COMPLEMENTARY AND ALTERNATIVE MEDICINE, <http://nccam.nih.gov/health/decisions/credentialing.htm> (last visited Jan. 28, 2012).

277. *State Licensure Requirements*, NATIONAL CERTIFICATION COMMISSION FOR ACUPUNCTURE AND ORIENTAL MEDICINE, <http://www.nccaom.org/regulatory-affairs/state-licensure-map> (last visited Jan. 28,

hours of study and completion of the National Certification Commission for Acupuncture and Oriental Medicine (NCCAOM) written exam or a state written exam.²⁷⁸ Licensure grants acupuncturists the right to practice in a legislatively designated scope of practice (i.e., a range of clinical services narrower than that of allopathic medicine). Licensed physicians are expressly permitted to perform acupuncture without additional training in 31 states, while 11 states require additional training (200-300 hours) or an examination, four states do not have any ruling, and two states do not permit physician acupuncture.²⁷⁹

CAM providers who exceed their scope of practice may be prosecuted for the unauthorized practice of medicine (a felony in many states).²⁸⁰ As with physicians, CAM providers may also face malpractice liability, disciplinary actions by their professional boards, and institutional restrictions on practice. Malpractice actions against CAM providers hold providers to a standard of care appropriate to the profession; for example, an acupuncturist is held to the same standard as other acupuncturists.²⁸¹ The plaintiff in a malpractice case against a CAM provider has the burden of proving that such provider did not meet “the degree of knowledge and skill possessed or the degree of care ordinarily exercised” by practicing CAM providers in similar communities and under similar circumstances.²⁸² Reference to the individual profession’s standard of care to evaluate malpractice is usually a matter of common law, although in some states a statutory definition is provided.²⁸³

CAM providers may also face malpractice liability for failure to refer patients to allopathic providers and for misrepresentation. The duty to refer may include the duty to determine whether the patient has a condition treatable through CAM, to refrain from providing treatment when a reasonable practitioner should be aware the condition will not be responsive to further treatment, and to inform patients that certain conditions are not treatable through CAM. This may include a duty to refer

2012).

278. David M Eisenberg et al., *Credentialing Complementary and Alternative Medicine Providers*, 137 *Ann Intern Med* 965, 966 (2002).

279. *Id.*

280. Each state licenses physicians and defines the practice of medicine then makes it a crime for anyone other than a licensed medical doctor to undertake those activities. JAMES M HUMBER AND ROBERT F ALMEDER, *ALTERNATIVE MEDICINE AND ETHICS* 138 (Humana Press, 1998).

281. Carolyn Chambers Clark & Rena J. Gordon, *Legal Rules Affecting Complementary Practice: Malpractice and Vicarious Liability*, in *ENCYCLOPEDIA OF COMPLEMENTARY HEALTH PRACTICE* 85 (1999).

282. *Id.*

283. Nancy Faass, *Integrating Complementary Medicine into Health Systems*, 229 (Jones & Bartlett, 2001).

to an allopathic provider when appropriate.²⁸⁴ When CAM providers make claims exceeding their training and ability, they are liable for misrepresentation. A plaintiff alleging misrepresentation must introduce evidence of intent to defraud, deceive, or misrepresent on behalf of the CAM provider.²⁸⁵ This may be provided by expert testimony if the relevant CAM community would not accept the provider's claims. Additionally, CAM providers may be held to medical standards of care where professional practice overlaps.²⁸⁶ CAM providers face a lower incidence of malpractice litigation²⁸⁷ than conventional providers, and there is minimal case law on malpractice claims against CAM providers.²⁸⁸ In part, this is due to the low-risk nature of CAM and differences in scope of practice, and also because CAM providers tend to have a more collaborative provider-patient relationship.²⁸⁹

In terms of CAM services, there appears to be adequate consumer protection, particularly in light of the non-invasive nature of CAM treatments. However, consumers and CAM providers would likely benefit from the creation of uniform and widely adopted institutional policies, scopes of practice for CAM providers, and standards of care.

CAM in PPACA—The Evidence-Based Complementary and Alternative Medicine Act

There are a variety of mechanisms to include in the Patient Protection and Affordable Care Act (PPACA) amendment—The Evidence-Based Complementary and Alternative Medicine Act—to potentially improve CAM use, lower health care costs, and benefit public health. Insurance reimbursement for evidence-based CAM treatments, as determined by an independent panel of experts, should be mandated. Improved research on CAM is vital to determine what CAM is “evidence-based” and to integrate effective CAM with mainstream health care. Existing government subsidies for CAM research should be increased, and new mechanisms for stimulating private sector CAM R&D should be considered. Government prizes to incentivize research on existing CAM products, possibly granted

284. A chiropractor's failure to inform a patient of a possible herniated disc and to refer that patient to a physician has been held to constitute malpractice, as has failure to refer a fracture to a medical doctor. *Id.* at 231.

285. *Id.* at 230.

286. *Id.*

287. David M. Studdert et al., *Medical Malpractice Implications of Alternative Medicine*, 280 JAMA 1610, 1614 (1998) (describing malpractice liability of physicians for referrals to CAM providers).

288. *Id.* at 230.

289. *Id.*

for FDA approval of a CAM product in an NDA, would incentivize R&D on CAM products. A market exclusivity regime provided to evidence-based CAM treatments approved by the FDA in a New Drug Application modeled after the Orphan Drug Act would likewise incentivize R&D on CAM products. Insurance reimbursement for CAM products approved in an NDA that would otherwise qualify for approval as a dietary supplement could be mandated to provide a further stimulus. Some form of cost control may be necessary to prevent unfair pricing, for example, through anti-trust legislation or compulsory licensing. *Sui generis* laws are another possible mechanism for promoting CAM-based innovations.

PPACA should empower an existing government agency to focus on CAM policy. PPACA is chartered to create the National Diabetes Prevention Program, the National Prevention, Health Promotion and Public Health Council, and the Patient-Centered Outcomes Research Institute. There is also a need for an agency to develop guidelines to address topics including national policies on CAM, best practices, licensing and credentialing issues, institutional policies, and education and training of CAM practitioners. Such an agency could play a valuable role in centralized coordination of federal efforts regarding CAM. The National Center for Complementary and Alternative Medicine (NCCAM) does not currently perform this role as it is primarily a research center.²⁹⁰ However, given NCCAM's unique expertise on CAM among government agencies, it may be the most suitable candidate to address these issues and coordinate Federal CAM activities.²⁹¹ NCCAM may also be a better fit than the USPSTF to recommend evidence-based CAM services given the agency's expertise in this specialized subject matter. NCCAM could establish an independent panel of experts to conduct regular scientific evidence reviews of CAM and to make recommendations.

CAM should also be included in PPACA to support the right of Americans to involve themselves in their own health care. Over thirty years ago, the Alma Ata Declaration affirmed that "people have the right

290. "The mission of NCCAM is to define, through rigorous scientific investigation, the usefulness and safety of complementary and alternative medicine interventions and their roles in improving health and health care." *NCCAM Facts-at-a-Glance and Mission*, NATIONAL CENTER FOR COMPLEMENTARY AND ALTERNATIVE MEDICINE, <http://nccam.nih.gov/about/ata glance/>.

291. The White House Commission on CAM recommended the Secretary of Health and Human Services to create a policy advisory committee to "address issues related to providing access to qualified CAM practitioners, provide guidance to the states concerning regulation possibilities, and provide a forum for dialogue on other issues related to maximizing access." White House CAM Commission, *supra* note 161, at 95. It also recommended an office be created within the Department of Health and Human Services to "coordinate Federal CAM activities and to facilitate the integration into the nation's health care system of those complementary and alternative health care practices and products determined to be safe and effective." White House CAM Commission, *supra* note 161, at 140.

and duty to participate individually and collectively in the planning and implementation of their health care.”²⁹² The popular use of CAM is a clear indication that Americans consider it to be an important part of their health care. In 1994, after an attempt by the FDA to restrict commercial availability of dietary supplements, approximately two million letters were sent to members of Congress to fight for consumer access.²⁹³ In justifying the resulting Dietary Supplement and Health Education Act, Congress cited “overwhelming public pressure” favoring improved access.²⁹⁴

It would be politically challenging to include CAM in PPACA. However, the focus on preventive and wellness-based approaches to care was also controversial, as was the Act itself. Ultimately, political leadership is necessary to include CAM in PPACA. Political leadership resulted in the establishment of the Office of Alternative Medicine, which was controversial in 1991 and largely opposed by the conventional medical community. Today, NCCAM is more widely accepted, and it has made significant progress toward scientific evaluation of CAM. NCCAM was praised in the White House Commission for its leadership and contributions to CAM research, and the Commission recommended increasing the center’s activities.²⁹⁵

Challenges

The most significant barrier to incorporating CAM into mainstream medicine is the fact that most CAM treatments lack scientific evidence of safety and efficacy. As stated in an article in the *New England Journal of Medicine*, “It is time for the scientific community to stop giving alternative medicine a free ride. There cannot be two kinds of medicine—conventional and alternative. There is only medicine that has been adequately tested and medicine that has not, medicine that works and medicine that may or may not work. Once a treatment has been tested rigorously, it no longer matters whether it was considered alternative at the outset. If it is found to be reasonably safe and effective, it will be accepted.

292. *International Conference on Primary Health Care, Declaration of Alma-Ata*, WORLD HEALTH ORGANIZATION, http://www.who.int/hpr/NPH/docs/declaration_almaata.pdf; *Background of WHO Congress on Traditional Medicine*, WORLD HEALTH ORGANIZATION, http://www.who.int/medicines/areas/traditional/congress/congress_background_info/en/index.html (last visited Jan. 28, 2012).

293. INSTITUTE OF MEDICINE, *COMPLEMENTARY AND ALTERNATIVE MEDICINE IN THE UNITED STATES* 258 (2005).

294. Lauren J. Sloane, *Herbal Garden of Good and Evil: The Ongoing Struggle of Dietary Supplement Regulation*, 51 ADMIN. L. REV. 323, 332 (1999).

295. White House CAM Commission, *supra* note 161, at 31.

But assertions, speculation, and testimonials do not substitute for evidence. Alternative treatments should be subjected to scientific testing no less rigorous than that required for conventional treatments.”²⁹⁶

The answer to this criticism is to provide increased funding for research on CAM. Research should not be less rigorous than that applied to conventional treatments, but at the same time, it must take into account the unique challenges posed by studying CAM modalities. Without more research in CAM, the evidence-base for CAM will remain unchanged, as will the reluctance of those that favor conventional medicine to endorse CAM treatments.

Incentivizing private research, whether through subsidies, grants, market exclusivity or *sui generis* laws is not without risks. Private capital, like government funding, is finite, and spending on R&D for CAM might otherwise be spent on research for new allopathic treatments. Providing for stronger ownership rights for CAM also risks introducing some of the same problems that exist in conventional privately funded research. For example, privately funded research runs the risk of study bias. Where a manufacturer stands to gain or lose tremendous sums of money based on the outcome of clinical trials, researchers have reported pressure to alter study design, methodology or results. A 2005 study surveyed 3,247 U.S. researchers publicly funded by NIH and found that 15.5% of those conducting studies admitted to altering design, methodology or results of their studies due to pressure from an external funding source. The authors report, “Our findings suggest that U.S. scientists engage in a range of behaviors extending far beyond falsification, fabrication and plagiarism.”²⁹⁷ Another 2005 study published in the *New England Journal of Medicine* reported that standards for clinical-trials with industry sponsors vary considerably among the 107 medical research institutions questioned. In fact, 24% of institutions allowed sponsors to insert their own statistical analyses in manuscripts, 50% allowed sponsors to draft manuscripts, and 41% allowed sponsors to prohibit investigators from sharing data with third parties after the trial.²⁹⁸

Investing in CAM may encounter resistance from the medical orthodoxy. CAM treatments tend to be low-tech and high-touch—the sort of care that is least economically desirable for physicians to perform.²⁹⁹ In

296. Marcia Angell & Jerome P. Kassirer, *Alternative medicine – The Risks of Untested and Unregulated Remedies*, 339(12) NEW ENG. J. MED. 839, 841 (1998).

297. Brian C. Martinson et al., *Commentary, Scientists Behaving Badly*, 435(9) NATURE 737, 737 (2005).

298. Michelle M. Mello et al., *Academic Medical Centers’ Standards for Clinical-Trial Agreements with Industry*, 352 NEW ENG. J. MED. 2202, 2202 (2005).

299. TS Bodenheimer & K. Grumbach, UNDERSTANDING HEALTH POLICY: CLINICAL APPROACH, NEW YORK

fact, most CAM does not require physician involvement, and physicians have historically opposed initiatives that would expand the role of allied health professionals, even for mainstream professionals such as Physician Assistants. It is therefore important that investment in CAM be done in a collaborative, rather than a competitive fashion. Investment in CAM should not undermine parallel markets such as the pharmaceutical market, and it should not be used at the expense of conventional care. Where CAM is found to be safe and effective, it should be incorporated into mainstream care with physician involvement, and included in integrative clinical models.

V. CONCLUDING THOUGHTS

The use of CAM in the U.S. is substantial, yet it continues to exist at the periphery of conventional medicine. As with preventive and wellness-based approaches to care, the Administration should include a focus on CAM in the Patient Protection and Affordable Care Act. This has the potential not only to improve CAM use, but also to improve the quality and cost of health care nationally. This model could prove safer, more affordable, and more effective in dealing with the health care challenges of the 21st century.