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Will Everyone Get Their Best Medicine? Implications for Off-Label Use of Pharmaceuticals in an American Universal Healthcare Regime

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WILL EVERYONE GET THEIR BEST MEDICINE? IMPLICATIONS FOR OFF-LABEL USE OF PHARMACEUTICALS IN AN AMERICAN UNIVERSAL HEALTHCARE REGIME

I. INTRODUCTION

Prescribing drugs for off-label uses has become a common practice among physicians both in the United States and abroad.¹ This is due in part to pharmaceutical companies that illegally promote off-label uses to doctors.² The prevalence of lawsuits against such companies suggests that large pharmaceutical companies prefer to suffer the consequences of violating drug promotion laws rather than spend the money and time to conduct clinical tests so that additional uses may be promoted legally.³ This idea can be rationalized when one compares the cost of post-market clinical tests and the short length of patent protections on certain drugs to the fact that doctors maintain the freedom to prescribe any drug for its off-label indications, and how drug companies can profit from this off-label use.⁴ Since it is arguable that doctors will continue to prescribe drugs for off-label uses they find effective without any accompanying Food and Drug Administration (FDA) approval, it is understandable why manufacturers will continue to find ways around marketing prohibitions to get the word to doctors about off-label indications of their products.

One important consideration is how the consistent use of off-label drugs affects Medicare and Medicaid payment schemes. Both federal programs will cover any drug use that has been approved by the FDA, and both will cover off-label uses that have been reviewed in a variety of sources that

1. See generally Elizabeth A. Weeks, *Is It Worth the Trouble? The New Policy on Dissemination of Information on Off-Label Drug Use Under the Food and Drug Administration Modernization Act of 1997*, 54 FOOD & DRUG L.J. 645 (1999) (discussing the prevalence of off-label prescribing in the absence of FDA oversight of physician prescribing practices).

2. See generally *id.* (discussing the illegal promotion of off-label uses by pharmaceutical manufacturers and the perceived benefits of promoting off-label uses).

3. Jonathan D. Rockoff, *Improper Sales of Medicines Targeted Drug Firms Have Paid Fines of \$3.5 Billion Since 2001 for Wrongful Promotions*, BALT. SUN, May 7, 2006, at 1A; Sandra H. Johnson, *Polluting Medical Judgment? False Assumptions in the Pursuit of False Claims Regarding Off-Label Prescribing*, 9 MINN. J. L. SCI. & TECH. 61, 67-68 (2008).

4. Johnson, *supra* note 3, at 69-71; see also Weeks, *supra* note 1, at 663 (discussing the shorter patent life of secondary indications).

make up the Congressional compendia.⁵ Beyond those drugs listed in the Congressional compendia, however Medicare Part D and individual state Medicaid programs tend to limit what kind of off-label uses they will pay for.⁶ How these government funded programs deal with off-label prescribing practices is important when predicting how the issue might be handled in a universal healthcare system.

This note will discuss how Medicare and Medicaid handle the issue of off-label prescribing, and will compare the United States' current approach with the approaches of two countries with universal health care coverage, the United Kingdom and Switzerland. This note will also examine how the United Kingdom and Switzerland reconcile the rising price of drugs with the necessity of controlling costs. Based on these models, this note will analyze how the off-label issue might be best handled if a universal health care system were to be implemented in the United States. Any proposal for universal healthcare in this country must consider the costs associated with providing such a system. Ultimately, if it is decided that off-label use is unnecessary or not cost-effective from the perspective of the insurer, it begs the question whether patients who rely on off-label drugs to treat chronic symptoms will be left by the wayside in an effort to provide everyone "adequate" care.

This note will first discuss the nature of off-label use in the U.S. and abroad, including the regulations pertinent to the approval and promotion of pharmaceuticals. After establishing in Section II that off-label use is likely to continue, Section III will then address the ways in which off-label drugs prescribed by doctors are covered under the federally funded Medicare insurance program and the federal and state funded Medicaid insurance program. These approaches will then be compared to how drugs are covered in U.K. and Switzerland. Section IV will consider several projected plans for universal healthcare programs in the United States and, using the Medicare and Medicaid models and the two European systems, will analyze implications for coverage of off-label use in an American universal health care scheme. Ultimately, this note concludes that the cost of off-label prescribing may eventually outweigh patient need in any potential universal healthcare regime.

II. OFF-LABEL USE OF PHARMACEUTICALS

Before considering different universal healthcare models, it is important to establish a general understanding of off-label activity. Off-label use has

5. 42 U.S.C. § 1395x(t)(2) (2000); 42 U.S.C. § 1396r-8(k) (2000).

6. 42 U.S.C. § 1395w-102 (Supp. IV 2004); see, e.g., *Edmonds v. Levine*, 417 F. Supp. 2d 1323, 1327-31 (S.D. Fla. 2006) (case concerning Florida's refusal to cover certain off-label uses under its state funded Medicaid program).

been defined as using a drug “for a purpose, in a higher or lower dose, over a longer period of time, or for a population (such as children) different from that for which the drug has been approved.”⁷ Off-label use also includes “administering the drug in an unapproved method,”⁸ or using an unapproved formulation.⁹ While promotion of off-label uses is strongly regulated, doctors are free to prescribe drugs for unapproved uses, and many commonly do.¹⁰ The practice of off-label prescribing is particularly prevalent with cancer and HIV/AIDS patients, as well as in pediatrics, due to the fact that most medicines for chronic diseases are approved for adults only.¹¹

A. *Off Label Use, Generally*

The rationale supporting off-label use relates to the idea that many patients are unable to wait for the FDA to approve a use of a drug that their doctor has found to be effective to treat certain diseases.¹² Off-label drug use is also supported by the idea that the cost to drug companies to seek approval of secondary indications of an already approved drug is too high.¹³ On- or off-label, drug companies profit from the use of their drugs, so there is very little incentive to undertake this time-consuming and costly process.¹⁴ Additionally, since drug companies conduct clinical trials in order to seek approval for universal distribution for the first indication of a drug, the company may use a significantly more “conservative risk/benefit calculus” than that used by an individual doctor assessing the needs of a patient in order to expedite the approval process.¹⁵ In other words, the

7. Johnson, *supra* note 3, at 61.

8. Weeks, *supra* note 1, at 647; see also Sharon Conroy et al., *Survey of Unlicensed and Off Label Drug Use in Paediatric Wards in European Countries*, 320 BRIT. MED. J. 79, 79-80 (2000).

9. Conroy et al., *supra* note 8.

10. Weeks, *supra* note 1, at 647.

11. Weeks, *supra* note 1, at 647-48; see generally Rosemary Roberts et al., *Pediatric Drug Labeling: Improving the Safety and Efficacy of Pediatric Therapies*, 290 JAMA 905, 905 (2003).

12. Katherine A. Helm, Note, *Protecting Public Health from Outside the Physician's Office: A Century of FDA Regulation from Drug Safety Labeling to Off-Label Drug Promotion*, 18 FORDHAM INTELL. PROP. MEDIA & ENT. L.J. 117, 164 (2007).

13. See generally Johnson, *supra* note 3, at 69-71 (arguing that “the [federal] regulatory structure incentivizes pharmaceutical firms to seek a narrow approved use, at least initially, in order to minimize the delay to market and reduce the investment in research required to meet FDA standards for approval.”).

14. *Id.* at 67-71 (noting that “the FDCA encourages the proliferation of off-label uses” because once a drug is approved for a single purpose, it is available for physicians to prescribe any way they see fit).

15. Weeks, *supra* note 1, at 659.

doctor is generally in a far better position to determine whether an off-label drug works for a particular patient. In fact, since the FDA considers the practice of medicine exclusively within the realm of the physician, and therefore out of its regulatory control, an off-label use that has proved effective in the treatment of various conditions is commonly accepted as standard practice by physicians.¹⁶ Some physicians even consider failure to prescribe drugs for known effective off-label uses as a potential malpractice liability.¹⁷

Conversely, there is substantial concern about the risk of adverse reactions to off-label uses that are not scientifically validated by the FDA approval process.¹⁸ A recent study found that while off-label use is relatively common, some occurs without any evidence of "therapeutic efficacy."¹⁹ That study also pointed out that while many off-label uses "represent a logical extension of the FDA-approved indication," some uses were nevertheless "distinctively different from those for which the drug was approved."²⁰ Even in situations where the drug is being used for the approved indication, off-label prescribing is common among untested populations, such as children, for whom the use of drugs only approved for adults could potentially present significant dangers.²¹ This is a cause for concern for policymakers as the primary goal of the FDA is patient welfare.²²

16. See Johnson, *supra* note 3, at 68 (discussing how an off-label use of a drug can become the "customary standard of care" in certain circumstances, and noting that the FDA lacks the authority to regulate the prescribing practices of health care practitioners).

17. Weeks, *supra* note 1, at 648; see generally Johnson, *supra* note 3, at 68 (stating that, "[i]n fact, off-label use often becomes the customary standard of care in particular circumstances, with the result that doctors are at risk for malpractice liability for failure to prescribe an approved drug for an off-label use.>").

18. Weeks, *supra* note 1, at 658; David C. Radley et al., *Off-Label Prescribing Among Office-Based Physicians*, 166 ARCHIVES INTERNAL MED. 1021, 1021, 1025 (2006) (observing that when off-label uses are similar to the approved indications, there is not much to be concerned about, but that some off-label uses are "for indications distinctly different from those for which the drug was approved", which presents cause for concern over patient safety); see also Valérie Junod, *Information et publicité pour les médicaments s'adressant aux Professionnells: les tribunaux Appliquent le droit de manière stricte*, 88 BULLETIN DES MÉDECINS SUISSES 1399, 1402 (2007) available at www.saez.ch/pdf_f/2007/2007-34/2007-34-427.pdf (last visited Jan. 3, 2009) (discussing the dangers of doctors not being able to access information on off-label uses of drugs they are prescribing).

19. Radley et al., *supra* note 18, at 1025.

20. *Id.* at 1025.

21. Johnson, *supra* note 3, at 82.

22. Weeks, *supra* note 1, at 658; see ENTERPRISE DIRECTORATE-GENERAL, EUROPEAN COMM'N, PHARMACEUTICALS IN THE EUROPEAN UNION 4, 8 (2000), available at <http://ec.europa.eu/enterprise/pharmaceuticals/pharmacos/docs/brochure/brochurenov>

B. Off-Label Prescribing Practices in the United States

In the interest of patient safety, promotion of off-label uses was prohibited entirely in the U.S. until 1997, when Congress passed the Food and Drug Administration Modernization Act (FDAMA).²³ FDAMA created a small exception for the dissemination of information by manufacturers about alternate uses of an already approved drug if that manufacturer was in the process of conducting trials for the new use, or if that manufacturer had already filed “a supplemental application to FDA for approval of the new use.”²⁴ This privilege is narrow, however, and subject to significant restrictions.²⁵ Among these restrictions are the rules that a manufacturer may only disseminate information that is considered “scientifically sound,” which can be demonstrated by publication in a peer-reviewed medical or scientific journal, or similar reference publication.²⁶ Additionally, such information may only be disseminated to healthcare practitioners, pharmacy benefit managers, health insurance issuers, group health plans, or federal or state government agencies.²⁷

Given the fact that companies must still conduct clinical testing and seek approval from the FDA if they want to promote an off-label use, at least one author argues that many companies will not take advantage of the dissemination privilege granted by FDAMA.²⁸ Clinical testing and approval application is a long and expensive process, and if drug companies can profit from the proliferation of off-label use of their products (through physician experimentation and word of mouth, among other methods), there may not be any incentive to seek approval for those off-label uses.²⁹ From the perspective of the pharmaceutical industry, obtaining FDA approval for

99.pdf (last visited Jan. 3, 2009) (discussing the similar goals of the European Union’s equivalent to the FDA, the European Agency for the Evaluation of Medicinal Products).

23. Food & Drug Administration Modernization Act of 1997 (FDAMA), Pub. L. No. 105-115, § 401; see Pub. L. No. 87-781, § 102(a)(1), 76 Stat. 781 (1962); see generally Weeks, *supra* note 1, at 653-54.

24. Weeks, *supra* note 1, at 650, 652; see 21 U.S.C § 360aaa(b)(1)(A) and (2000); see also Mitchell Oates, Note, *Facilitating Informed Medical Treatment Through Production and Disclosure of Research into Off-Label Uses of Pharmaceuticals*, 80 N.Y.U. L. REV. 1272, 1284 (2005).

25. 21 C.F.R. § 99.1 (2008); see Weeks, *supra* note 1, at 650-51.

26. 21 C.F.R. § 99.101(a); see also Weeks, *supra* note 1, at 650-51.

27. 21 C.F.R. § 99.1(a)(2) (2008); see also Weeks, *supra* note 1, at 650.

28. See generally Weeks, *supra* note 1, at 662 (arguing that the threat of sanctions and “the lack of additional economic incentives to seek FDA approval” will discourage companies from participating in the new dissemination procedure when they can still profit from “underground” promotion of off-label use of their drugs).

29. See *id.* at 663 (observing that “[m]anufacturers reap the economic benefits of increased sales of their products whether they are prescribed on- or off-label.”).

every possible use of a drug can be prohibitively expensive.³⁰ Currently, once a drug is approved for a relatively narrow use, it can be released into the market and off-label demand for it begins.³¹ Drug companies profit from the proliferation of information among doctors for off-label uses, which provides incentive from the market itself to not only approve drugs for very narrow indications (that is, the path of least resistance), but to disseminate information to doctors about off-label uses of their products by any means possible.³²

Further incentive for pharmaceutical companies to avoid conducting clinical tests on additional uses presents itself when patent protection of a drug does not last long enough to make such post-market testing profitable.³³ Obtaining FDA approval takes a significant amount of time, thus making it impractical to obtain approval for every possible indication.³⁴ Further, once allowed into the stream of commerce, both brand name and generic drugs will be prescribed off-label.³⁵ The fact that generic drugs are also prescribed for off-label uses has significant implications for any federal or state funded insurance program, where cutting costs it is important. This desire to reduce costs may push insurers to cover only generic forms of drugs. Thus, the incentives created for pharmaceutical companies by the market, insurers, and the current regulatory framework would seem to push those companies in the direction of promoting off-label use as a way of maximizing profits.

The fact that many pharmaceutical companies are embroiled in litigation related to the illegal promotion of off-label uses suggests that regulations concerning off-label promotion have not been able to overcome the financial incentives the marketplace has created for finding ways to inform doctors about profitable off-label uses.³⁶ Off-label promotion is generally not blatant, taking the form, for example, of providing doctors with gifts, giving them discounts on certain drugs, discussions about off-label uses behind closed doors, and other subtle, but improper, steps to provide incentives for the doctor to prescribe a certain drug.³⁷ Lawsuits filed against drug companies for illegal promotion of off-label indications have resulted

30. See *id.* at 662 (noting that “manufacturers may find the expense and effort of seeking new drug approval as a condition to dissemination of off-label information unjustified in comparison to the potential value of the approval.”).

31. Helm, *supra* note 12.

32. *Id.*

33. Weeks, *supra* note 1, at 663.

34. Johnson, *supra* note 3, at 69-71 (discussing low regulatory incentives for pharmaceutical companies to seek broad approval of new drugs).

35. Helm, *supra* note 12.

36. Rockoff, *supra* note 3.

37. *Id.*

in those companies paying multi-million dollar settlements.³⁸ Additionally, the federal False Claims Act has been employed repeatedly in cases where reimbursement by the Centers for Medicare and Medicaid Services (CMS) is involved.³⁹ The prevalence of litigation seems to indicate that, in terms of influencing pharmaceutical company decisions, the market incentives to engage in off-label promotion outweigh the penalties associated with regulations that prohibit such activity.⁴⁰ Even in cases where companies are self-regulated (i.e. they have internal compliance programs to combat illegal promotion activities), there is evidence that off-label promotion still occurs with alarming frequency.⁴¹ Efforts at self-regulation have been stepped up in recent months in light of the fact that drug companies continue to face litigation for illegal marketing practices, but not enough time has passed to determine if these measures will be effective at curbing this behavior.⁴² As a report issued by Consumers International, a consumer protection organization based in London, argues, "the sheer volume of reported breaches indicates that even the companies with apparently the most comprehensive compliance programmes are not fully effective in preventing breaches of marketing codes. This problem extends to the biggest companies, such as GSK [GlaxoSmithKline] and Pfizer."⁴³

38. See, e.g., *Bristol-Myers Squibb Will Pay \$515 Million to Settle Pricing, Marketing Allegations*, 5 *Pharmaceutical L. & Industry Rep.* (BNA) No. 39, at 1028 (Oct. 5, 2007); *Company Admits Drug Misbranding*, 5 *Pharmaceutical L. & Industry Rep.* (BNA) No. 29, at 746 (July 20, 2007); *OxyContin Maker Will Pay \$19.5 Million, Modify Marketing, in Settlement with States*, 5 *Pharmaceutical L. & Industry Rep.* (BNA) No. 19, at 486 (May 11, 2007); *Cell Therapeutics to Pay \$10.5 Million to Resolve Illegal Drug Marketing Charges*, 5 *Pharmaceutical L. & Industry Rep.* (BNA) No. 16, at 410 (Apr. 20, 2007) (all discussing settlements made by drug companies for violations of marketing laws).

39. See Johnson, *supra* note 3, at 101-17 (discussing the use of the FCA to garner a settlement of \$455 million over off-label use of the drug Neurontin).

40. See *id.* at 66 (noting that continued off-label prescribing suggests that litigation for violations seems to show the insignificance of the impact of such litigation).

41. Sarah Boseley, *Kickbacks, Cartels and Chatrooms: How Unscrupulous Drug Firms Woo the Public*, THE GUARDIAN (London), June 26, 2006, at www.guardian.co.uk/society/2006/jun/26/health.medicineandhealth1/print (last visited Jan. 3, 2009).

42. See Gardiner Harris, *Drug Industry to Announce Revised Code on Marketing*, N.Y. TIMES, July 10, 2008, at C4 (discussing new voluntary guidelines established by the pharmaceutical industry which ban giving doctors gifts as a promotional tool).

43. CONSUMERS INT'L, *BRANDING THE CURE: A CONSUMER PERSPECTIVE ON CORPORATE SOCIAL RESPONSIBILITY, DRUG PROMOTION AND THE PHARMACEUTICAL INDUSTRY IN EUROPE* 26 -27 (June 2006) available at www.consumersinternational.org/Shared_ASP_Files/Uploaded_Files/ECD91B6F-FE37-45C0-AE34-898BFB39C700_BrandingtheCure-fullreport.pdf (last visited Jan. 3, 2009).

C. Off-Label Prescribing Practices in the United Kingdom

The Consumers International report demonstrates that illegal off-label promotion practices are not isolated to the United States. Although Europe's regulatory structure seems more complicated than that of the United States, the regulations are essentially the same.⁴⁴ The European Union (EU) established the European Agency for the Evaluation of Medicinal Products, commonly referred to as the European Medicines Evaluation Agency (EMA), which has roughly the same responsibilities as the FDA, but at a supranational level.⁴⁵ However, EMA approval is not the only way a drug can be approved for use in the EU. National regulatory agencies can also approve drugs for use and then go through an application to have the approval mutually recognized by other Member States.⁴⁶ Nevertheless, a Union-wide Directive issued by the Parliament and the Council of the European Union states that "Member States shall prohibit any advertising of a medicinal product in respect of which a marketing authorization has not been granted in accordance with Community law."⁴⁷ This Directive is bolstered by international trade associations that establish self-regulation mechanisms for member pharmaceutical companies which restrict promotion of non-approved drug uses.⁴⁸

As a member of the European Union, the United Kingdom (U.K.) is subject to the oversight of the EMA.⁴⁹ There is a significant amount of off-label use in the U.K. just as there is in the United States, particularly in pediatric medicine.⁵⁰ In the U.K., such practice is commonly referred to as

44. Compare Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community Code Relating to Medicinal Products for Human Use, 2001 O.J. (L 311) 67 at art. 87 with Food & Drug Administration Modernization Act of 1997 (FDAMA), Pub. L. No. 105-115, § 401; see Pub. L. No. 87-781, § 102(a)(1), 76 Stat. 781 (1962) and 21 C.F.R. § 99 (2008).

45. ENTERPRISE DIRECTORATE-GENERAL, *supra* note 22, at 7.

46. *Id.*

47. Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community Code Relating to Medicinal Products for Human Use, 2001 O.J. (L 311) 67 at art. 87.

48. See INT'L FED'N OF PHARMACEUTICAL MFRS. & ASS'NS, CODE OF PHARMACEUTICAL MARKETING PRACTICES 7 (2006 Revision), available at www.ifpma.org/pdf/IFPMA-TheCode-FinalVersion-30May2006-EN.pdf (last visited Jan. 3, 2009); see also EUROPEAN FED'N OF PHARMACEUTICAL INDUS. AND ASS'NS, CODE ON THE PROMOTION OF PRESCRIPTION-ONLY MEDICINES TO, AND INTERACTIONS WITH, HEALTHCARE PROFESSIONALS 7 (2007), available at www.efpia.org/Objects/2/Files/code%20medicines%202007.pdf (last visited Jan. 3, 2009).

49. European Medicines Agency, About EMA – Structure, at www.emea.europa.eu/hms/aboutus/emeaoverview.htm (last visited Jan. 3, 2009).

50. See S. Conroy et al., *Unlicensed and Off Label Drug Use in Acute Lymphoblastic Leukaemia and Other Malignancies in Children*, 14 ANNALS OF ONCOLOGY 42, 42 (2003) (finding that "[n]inety per cent of babies in neonatal intensive care receive unlicensed or off

prescribing “unlicensed” drugs rather than “off-label use,” which extends the definition of the practice to include prescribing drugs that are not approved for any particular use at all, such as caffeine.⁵¹ While promotion of off-label indications is regulated extensively by the EU authorities, ensuring safe, effective and affordable healthcare is the responsibility of the Member States.⁵² The Medicines and Healthcare products Regulatory Agency (MHRA) is the British equivalent of the FDA and is responsible for approving various drug indications.⁵³ Managing authorities such as National Health Service (NHS) Trusts⁵⁴ or individual medical practices may further regulate and even prohibit off-label prescribing.⁵⁵ Additionally, the National Institute for Clinical Excellence (NICE) identifies and makes recommendations to the national healthcare authorities regarding which treatments are most effective and cost-efficient for patients.⁵⁶

While healthcare professionals in the U.K. believe that drug safety and efficacy are important, licensing status was only ranked tenth out of twelve choices in a survey of healthcare professionals addressing the prioritization of pediatric medication.⁵⁷ This relative lack of concern about licensing status seems to reflect the same attitude that American doctors often have

label drugs; 65% of prescriptions are unlicensed or off label. Seventy per cent of children in paediatric intensive care receive unlicensed or off label drugs.”); see also Ian Wong et al., *Paediatric Medicines Research in the UK: How to Move Forward?*, 26 *DRUG SAFETY* 529, 530 (2003) (observing that “[t]here have been numerous studies to show that many of the medicines used in children are used off-label or are unlicensed for use in children.”).

51. P. Hill, *Off Licence and Off Label Prescribing in Children: Litigation Fears for Physicians*, 90 *ARCHIVES OF DISEASE IN CHILDHOOD (SUPPLEMENT 1)* i17, i17 (2005); Conroy et al., *supra* note 50.

52. See Markus Hartmann & Florence Hartmann-Vareilles, *Recent Developments in European Pharmaceutical Law 2004: A Legal Point of View*, 39 *DRUG INFO. J.* 193, 203-04 (2005), available at www.diahome.org/NR/rdonlyres/39B6663D-0BA9-4666-A7F9-D598E851442E/0/DIJ39_2_193.pdf (last visited Jan. 3, 2009) (discussing how “public health remains a subject of complex national and inter-Member-State actions” and how Member States can decide the degree to which they will protect public health within the confines of the EC treaty).

53. Hill, *supra* note 51, at i17; see also Medicines and Healthcare products Regulatory Agency, at www.mhra.gov.uk/index.htm (last visited Jan. 3, 2009).

54. For an explanation of NHS Trusts, see National Health Service, About the NHS: NHS Authorities and Trusts, at www.nhs.uk/aboutnhs/howtheNHSworks/authoritiesandtrusts/Pages/Authoritiesandtrusts.aspx (last visited Jan. 3, 2009).

55. Hill, *supra* note 51, at i17.

56. Andrew Dillon et al., *The National Institute for Clinical Excellence and Coverage of Relenza by the NHS*, in *INFORMING JUDGMENT: CASE STUDIES OF HEALTH POLICY AND RESEARCH IN SIX COUNTRIES* 137, 144, 146, (2001).

57. Wong et al., *supra* note 50, at 531 tbl.1 (noting that safety, efficacy and characteristics of the disease, among other factors, ranked above licensing status as “most relevant when prescribing paediatric medications”).

regarding prescribing off-label. Further, the Consumers International Report shows that pharmaceutical companies approach the market in the U.K. the same way they do in the U.S., knowing that there is a significant market for off-label use.⁵⁸

D. Off-Label Prescribing Practices in Switzerland

Switzerland is not a member of the EU, and thus is not subject to the approval process of the EMEA or the directives of the Parliament and the Council.⁵⁹ The Swiss Agency for Therapeutic Products, otherwise known as Swiss Medic, is the Swiss equivalent of the FDA and the MHRA, and oversees how new drugs are approved and promoted in Switzerland.⁶⁰ Switzerland has laws similar to those of the U.S. and the EU prohibiting the dissemination of information regarding unapproved uses of medicines.⁶¹ The *Loi sur les produits thérapeutiques* (LPT) (Law on Therapeutic Products) and *l'Ordonnance sur la publicité pour les médicaments* (OPMéd) (Ordinance on the Advertising of Medicines) strictly regulate communication by pharmaceutical companies directed toward physicians pertaining to new drugs.⁶² Article 2, letter (a) of OPMéd defines *publicité* ("advertising") as "toute forme d'information, de prospection ou d'incitation qui vise à encourager la prescription, la remise, la vente, la consommation ou l'utilisation de médicaments" (that is, any form of information, canvassing, or inducement designed to promote the prescription, delivery, sale, consumption or use of a drug).⁶³ This provision has been interpreted to even include messages that are purely informative and objective if they have

58. CONSUMERS INT'L, *supra* note 43.

59. U.S. Dep't of State, Bureau of Public Affairs: Electronic Information and Publications Office, Background Note: Switzerland, at "History", at www.state.gov/r/pa/ei/bgn/3431.htm (last visited Jan. 3, 2009).

60. Swissmedic, Our Core Business: About Swissmedic: Swissmedic, at www.swissmedic.ch/en/industrie/overall.asp?theme=0.00098.00001&theme_id=512 (last visited Jan. 3, 2009).

61. See generally Junod, *supra* note 18, at 1399 (a Swiss article discussing [in French] three 2006 decisions on off-label promotion of drugs in Switzerland rendered by the *Commission recours pour les produits thérapeutiques* [Appeals Committee for Therapeutic Products] under the *loi sur les produits thérapeutiques* [law on Therapeutic Products] and *l'Ordonnance sur la publicité pour les médicaments* [Ordinance on the Advertising of Medications]).

62. *Id.* at 1400; Federal Law on Medicinal Products and Medical Devices (Law on Therapeutic Products - LTP), arts. 31-33 (2007) (Switz.); *Ordonnance sur la publicité pour les médicaments* [OPMéd] [Ordinance on the Advertising of Medicines] Oct. 17, 2001, 812.212.5 art. 2.a (Switz.).

63. *Ordonnance sur la publicité pour les médicaments* [OPMéd] [Ordinance on the Advertising of Medicines] Oct. 17, 2001, 812.212.5 art. 2.a (Switz.).

the effect of increasing sales.⁶⁴ In order to avoid the label of “advertising,” and thus falling into a category of communication subject to strict regulation and often prohibited, a communication from a pharmaceutical company cannot identify any certain drug or any particular class of drugs.⁶⁵ However, manufacturers are required to communicate information to physicians regarding the safety and efficacy of their drugs, and this communication is considered legal as long as it does not result in increased drug sales.⁶⁶ The central idea is that no information can be disseminated which could have the effect of increasing sales and therefore producing profit for the drug companies.⁶⁷

As is the case in many other countries, off-label drug use is common in Switzerland, particularly in pediatrics.⁶⁸ While Swiss off-label promotion laws are stricter than those in the U.S., physicians still maintain prescribing freedom in Switzerland.⁶⁹ SwissMedic only approves the marketing of a drug for the indications of that drug which have been verified by a thorough evaluation of pharmaceutical interest, quality, and the overall safety of the drug.⁷⁰ Similarly, drug makers are not allowed to disseminate any information that is outside the scope of the drug’s approval, including any favorable results of clinical studies on non-approved uses, even if those results are incontestable.⁷¹ Further, SwissMedic forbids communication about non-approved uses on Swiss public internet sites.⁷² If a manufacturer wants to publicize such information, it must first seek modification of the drug’s approved indications from SwissMedic, a stricter regulation than FDAMA’s requirement that a company be simply actively seeking approval of the off-label indication before disseminating such information.⁷³

Since doctors are free to prescribe drugs as they wish, there is concern that the prohibition of publicizing positive results of drug studies will prevent a physician from gaining a complete understanding of the drugs he or she

64. Junod, *supra* note 18, at 1400.

65. *Id.*

66. *Id.* at 1400, 1403 n.12.

67. See *id.* at 1401 (noting that the practice of off-label prescribing is legal in Switzerland).

68. Ermindo R. Di Paolo et al., *Unlicensed and Off-Label Drug Use in a Swiss Paediatric University Hospital: A Pilot Study*, 136 SWISS MED. WKLY. 218, 220, 221 (2006).

69. Junod, *supra* note 18, at 1401.

70. E.R. Di Paolo et al., *Incidence des prescriptions hors autorisation de mise sur le marché dans le département médico-chirurgical de pédiatrie d’un chu Suisse*, Congrès annuel de la Société Suisse de Pédiatrie, Davos, June 26-28, 2003, available at www.chuv.ch/pha/pha_poster_ssp-amm.pdf (last visited Jan. 3, 2009).

71. Junod, *supra* note 18, at 1400.

72. *Id.* at 1402.

73. *Id.* at 1401; see also *supra* notes 23-27 and accompanying text.

prescribes.⁷⁴ In light of the common off-label uses of many drugs, and the concerns surrounding such uses, SwissMedic has taken measures to promote increased approval for off-label and unlicensed drugs, particularly those used in pediatrics.⁷⁵ One notable action that SwissMedic has taken is to extend the patent protection for pharmaceutical companies who voluntarily research uses of drugs that are currently used off-label in children.⁷⁶ Since inadequate patent protection is one of the factors that arguably contributes to the reluctance of pharmaceutical companies to seek approval of off-label indications,⁷⁷ this protection may lead to a reduction in the prevalence of off-label and unlicensed drug use in Switzerland.

Given that physician autonomy is consistently honored in Switzerland,⁷⁸ as well as in the U.K., it seems off-label prescribing will remain a common practice in the absence of significant changes to the regulatory framework of these countries. The frequency of off-label prescribing complicates how insurance providers differentiate between drugs that will and will not be covered. This uncertainty is particularly relevant to government-funded insurance programs, where cost is an important concern. In the United States, voters are significantly divided on this issue. Some believe that the government should provide everyone with affordable healthcare, while others worry about how such an approach would be financed, and whether the government is really capable of providing adequate healthcare coverage on such a large scale.⁷⁹ This concern already puts any potential American universal healthcare system in a vice, particularly with regard to prescription drug coverage, as legislators grapple with how to provide efficient coverage that keeps costs low while maintaining superior quality for all patients.

74. Junod, *supra* note 18, at 1401.

75. Di Paolo et al., *supra* note 70, at 220.

76. *Id.*

77. See Weeks, *supra* note 1, at 663 (discussing the shorter patent life of secondary indications).

78. See Junod, *supra* note 18, at 1401 (noting that off-label prescribing is legal in Switzerland and often conforms to the standards of good medicine); see also Weeks, *supra* note 1, at 647 (noting how the FDA “has disavowed any authority to regulate the off-label prescribing practices of individual physicians.”); see also Johnson, *supra* note 3, at 68-69 (discussing how an off-label use of a drug can become “the customary standard of care” in certain circumstances, and how the FDA lacks the authority “to ‘limit or interfere with the authority of a health care practitioner to prescribe or administer any legally marketed [medical] device to a patient for any condition or disease within a legitimate health care practitioner-patient relationship.’”).

79. Robin Toner & Janet Elder, *Most Support U.S. Guarantee of Health Care*, N.Y. TIMES, Mar. 2, 2007, at A1.

III. GOVERNMENT FUNDED HEALTHCARE

A. *Government Funded Insurance in the United States*

In the U.S., the concept of government-funded healthcare is relatively foreign, compared to other countries.⁸⁰ Currently, federal programs such as Medicare and Medicaid are two of the primary ways that the U.S. government funds healthcare. These programs provide health insurance to senior citizens, disabled individuals, and the poor.⁸¹ Together, Medicare and Medicaid provide medical and prescription drug coverage to approximately eighty million people.⁸² Because Medicare and Medicaid provide healthcare coverage for approximately one third of the U.S. population,⁸³ these programs are good models to examine when considering how an American universal healthcare regime might be structured.

Medicare and Medicaid present two different ways in which the government works to reconcile the competing goals of patient welfare and cost containment in the context of reimbursement for off-label drug use. Since off-label use is not an exclusively American phenomenon, this note will consider the approaches used in the U.K. and Switzerland to balance patient welfare and cost containment in an effort to analyze how those approaches may provide a model for the United States. Healthcare in the U.K. emphasizes cost-effectiveness, as scarce healthcare resources must be rationed among many patients, all of whom receive free healthcare at the point of service.⁸⁴ Switzerland mandates that every individual who can afford to buy comprehensive health insurance does so, and the cost of the premium is set by the government in an effort to “bring more solidarity” to

80. See The University of Pennsylvania, Wharton School of Business, ‘*Harry and Louise, the Sequel? The Universal Health Care Debate is Back*, KNOWLEDGE@WHARTON, June 27, 2007, at <http://knowledge.wharton.upenn.edu/article.cfm?articleid=1761> (last visited Jan. 3, 2009) (discussing how public opinion has affected prospects for universal healthcare in the United States, and how the views of American citizens compare with those of citizens of countries with strong universal healthcare systems).

81. Social Security Amendments of 1965, Pub. L. No. 89-97, 79 Stat. 286 (1965); see also Alma Koch, *Financing Health Systems*, in INTRODUCTION TO HEALTH SERVICES 76, 78 (Stephen J. Williams & Paul R. Torrens eds., 7th ed. 2007).

82. CARMEN DENAVAS-WALT ET AL., U.S. CENSUS BUREAU, INCOME, POVERTY, AND HEALTH INSURANCE COVERAGE IN THE UNITED STATES: 2006, CURRENT POPULATION REPORTS: CONSUMER INCOME 20 (2007).

83. Koch, *supra* note 81, at 78; see Central Intelligence Agency, *The World Factbook: The United States*, at www.cia.gov/library/publications/the-world-factbook/geos/us.html (last visited Jan. 3, 2009) (As of July 2008, the population of the U.S. was estimated to be 303,824,640).

84. Dillon et al., *supra* note 56, at 144, 146.

the Swiss healthcare system.⁸⁵ Since the government subsidizes the cost of healthcare for citizens who cannot afford it, and since the government feels pressure from voters to keep premiums low, cost-containment is an important issue for the Swiss government.⁸⁶ An examination of the British and Swiss healthcare systems indicates how cost-effectiveness may affect coverage for off-label prescription drugs, and provides lessons that may be incorporated into an American healthcare system.

1. Medicare

Medicare is a federal program designed to provide healthcare services to senior citizens and disabled individuals.⁸⁷ Designed as a federal entitlement program, Medicare was established by the Social Security Act of 1965 and helps pay for hospital stays, outpatient treatment, and prescription drugs.⁸⁸ Medicare is divided into four parts: Part A covers hospital insurance benefits,⁸⁹ Part B covers outpatient therapies administered in a doctor's office,⁹⁰ Part C covers the Medicare+Choice Program,⁹¹ and Part D covers a voluntary prescription drug benefit.⁹² Part D was established under the Medicare Modernization Act of 2003 (MMA), and stipulates that prescription drug coverage be designed and administered by private insurance Prescription Drug Plans (PDPs) that are then reimbursed by the government.⁹³ Unlike Parts A and B, Part D is not standardized, giving individual private health insurance providers the freedom to determine what drugs they will cover, as long as those drugs are not specifically excluded from coverage by Medicare.⁹⁴

Chemotherapy and other outpatient drug treatments that are administered at a doctor's office are covered under Part B.⁹⁵ As nearly fifty percent of the uses of anticancer chemotherapy drugs are off-label, Congress has had to address the issue of off-label use under this part of

85. Interview by Frontline with Pascal Couchepin, President of Switzerland (Oct. 30, 2007) at www.pbs.org/wgbh/pages/frontline/sickaroundtheworld/interviews/couchepin.html (last visited Jan. 3, 2009) [hereinafter Couchepin Interview].

86. *Id.*

87. Koch, *supra* note 81, at 78.

88. *Id.* at 86-90; see also Social Security Amendments of 1965, Pub. L. No. 89-97, 79 Stat. 286 (1965).

89. 42 U.S.C. §§ 1395c - 1395i-5 (2000 & Supp. IV 2004).

90. 42 U.S.C. §§ 1395j - 1395w-4 (2000 & Supp. IV 2004).

91. 42 U.S.C. §§ 1395w-21 - 1395w-28 (2000 & Supp. IV 2004).

92. 42 U.S.C. § 1395w-102 (Supp. IV 2004).

93. BARRY R. FURROW ET AL., HEALTH LAW: CASES, MATERIALS AND PROBLEMS 781-85 (6th ed. 2008); Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, 117 Stat. 2066 (2003).

94. See FURROW ET AL., *supra* note 93, at 782-83.

95. *Id.* at 777; 42 U.S.C. § 1395k(a)(2) (2000 & Supp. IV 2004).

Medicare.⁹⁶ Congress enacted the Omnibus Budget Reconciliation Act (OBRA) in 1993, which required Medicare to cover off-label uses of anticancer drugs included in designated medical compendia.⁹⁷ OBRA works in conjunction with the provisions of the Social Security Act (SSA) which require that Medicare cover drugs for both FDA-approved indications and off-label uses supported in the American Hospital Formulary Service-Drug Information⁹⁸ or in the U.S. Pharmacopoeia-Drug Information.⁹⁹ The Secretary of Health and Human Services (HHS) may designate additional compendia as references that support certain off-label uses, as well as identify peer-reviewed medical journals that may offer guidance to Medicare contractors about off-label uses that are supported by clinical data.¹⁰⁰

Under Part D, the Medicare statute references the provisions of the Medicaid statute that cover drugs approved by the FDA and those that were in use before 1962, but does not refer directly to the definition of “medically necessary” that requires consulting the three compendia.¹⁰¹ If this part of the Medicare statute is to be interpreted explicitly, it would only cover FDA-approved drugs.¹⁰² A report issued by a patients’ rights group shows how such a strict interpretation of the statute under the Bush administration resulted in the loss of coverage for some people of off-label uses that were covered prior to switching to Medicare’s Part D plan.¹⁰³

Even when the statute is read more inclusively, Part D still only covers FDA-approved drugs and drugs that are found in one of the three

96. Am. Soc’y Clinical Oncology, *Reimbursement for Cancer Treatment: Coverage of Off-Label Drug Indications*, 24 J. CLINICAL ONCOLOGY 3206, 3206 (2006).

97. Pub. L. No. 103-66, 1107 Stat. 312 (1993); § 13553, 107 Stat. 591-92; Am. Soc’y of Clinical Oncology, *supra* note 96.

98. 42 U.S.C. § 1395x(t)(2) (2000); Am. Soc’y of Health-System Pharmacists, AHFS Drug Information: Off-Label Use, at www.ahfsdruginformation.com/off_label/index.aspx (last visited Jan. 3, 2009).

99. 42 U.S.C. § 1395x(t)(2) (2000); U.S. Pharmacopeial Convention, USP-NF-An Overview, at www.usp.org/USPNF/ (last visited Jan. 3, 2009); see also Am. Soc’y Clinical Oncology, *supra* note 96, at 3206 (noting that the even though the statute references the American Medical Association Drug Evaluation, this third compendium has been merged into the U.S. Pharmacopoeia-Drug Information).

100. 42 U.S.C. § 1395x(t)(2) (2000); Am. Soc’y Clinical Oncology, *supra* note 96, at 3207.

101. 42 U.S.C. § 1395w-102(e) (Supp. IV 2004); *Part D Denial of Access to ‘Off-Label’ Drugs Based on Misreading of Statute, Report Says*, 5 Pharmaceutical L. & Industry Rep. (BNA) No. 32, at 834 (Aug. 10, 2007); MEDICARE RIGHTS CTR., OFF-BASE: THE EXCLUSION OF OFF-LABEL PRESCRIPTIONS FROM MEDICARE PART D COVERAGE 7 (2007), available at www.medicarerights.org/Off-label_PartD_Coverage.pdf (last visited Jan. 3, 2009).

102. MEDICARE RIGHTS CTR., *supra* note 101.

103. *Id.*

compendia cited in the Medicaid statute.¹⁰⁴ However, there is no means for compendia expansion by the Secretary of HHS under Part D as there is under Part B.¹⁰⁵ According to one patient advocacy group, Part D is significantly narrower in its coverage of off-label use, and it lacks any sort of effective appeal procedure when a patient is denied coverage.¹⁰⁶

This difficulty with coverage of off-label uses under Part D is the subject of a recent complaint filed in the Southern District of New York against Michael O. Leavitt, in his official capacity as the Secretary of HHS.¹⁰⁷ The complainant, Judith Layzer, was a cancer survivor who has used the drug Cetrotide off-label since 1999 to treat and limit her cancer.¹⁰⁸ This off-label use of the drug was covered by Ms. Layzer's employer sponsored insurance before she switched to prescription drug coverage under Part D, at which point, she was faced with the option of no coverage or, alternatively, co-payments exceeding \$7,000.¹⁰⁹ The complaint alleged that the Secretary of HHS was wrong in determining that the complainant's off-label use of Cetrotide was unlawful because it was not FDA-approved or included in one of the three compendia, despite her doctors' repeated statements regarding the medical necessity of the drug to treat her cancer.¹¹⁰ When Layzer appealed the initial denial of her coverage to the Office of Medicare Hearings and Appeals, the Administrative Law Judge (ALJ) that heard her case admitted that the medical necessity of her therapy had "been firmly established by three prominent and highly qualified physicians who [were] familiar with" complainant's "uniquely serious medical condition", but nevertheless had to rule that coverage was not covered by Medicare Part D.¹¹¹ The ALJ noted that peer-reviewed literature supported the use of Cetrotide to treat ovarian cancer, and that his ruling created a discrepancy in Medicare coverage as the use would have been covered under Part B.¹¹²

Whether interpreted strictly or more broadly, by considering everything covered by the Medicaid statute, off-label prescription drug coverage is

104. 42 U.S.C. § 1395w-102(e) (Supp. IV 2004); 42 U.S.C. § 1396r-8(k)(2)-(6) (2000); Letter from Medicare Access for Patients Rx to Max Baucus, Senate Finance Committee Chairman, United States Senate (Nov. 15, 2007) available at www.medicarerights.org/maprxlettertobaucus.pdf (last visited Jan. 3, 2009), [hereinafter MAPRx Letter].

105. *Patient Advocates Urge Changes to Medicare to Allow Broader Coverage of Off-Label Drugs*, 46 *Pharmaceutical L. & Industry Rep.* (BNA) No. 46, at 1233 (Nov. 30, 2007).

106. MAPRx Letter, *supra* note 104.

107. Complaint at 1-3, *Judith M. Layzer & Ray J. Fischer v. Michael O. Leavitt*, No. 07-CV-11339 (S.D.N.Y. Dec. 18, 2007).

108. *Id.* at 3.

109. *Id.* at 8-9.

110. *See id.* at 7, 18-19.

111. *Id.* at 10.

112. Complaint at 10, *Judith M. Layzer & Ray J. Fischer v. Michael O. Leavitt*, No. 07-CV-11339 (S.D.N.Y. Dec. 18, 2007).

significantly limited by the Medicare Part D Prescription Drug Benefit.¹¹³ Unlike Part B, which is provided by Medicare directly and is funded through beneficiary premiums and general revenue funds,¹¹⁴ Part D benefits are provided by private PDPs, which are awarded contracts with HHS based on their bids for various coverage areas.¹¹⁵ The PDPs are only required to meet certain minimum coverage conditions, but other terms and conditions can be negotiated with HHS; consequently, plans can vary from the “standard coverage” elements listed in the legislation as long as they substitute “actuarially equivalent” coverage.¹¹⁶

Since PDPs must bid to receive contracts from HHS to provide prescription drug coverage,¹¹⁷ and are thus significantly influenced by market forces, it seems unlikely that they will offer coverage of drugs that are not explicitly required by Medicare and which cost more than the benefit the PDP would derive from covering the drug. This idea is evidenced by the fact that off-label coverage is much more inclusive under Part B (which is provided directly by Medicare)¹¹⁸ than it is under Part D.

2. Medicaid

The Medicaid program was established as a joint federal-state funded welfare program to assist states with healthcare costs for the poor.¹¹⁹ Although “states are not required to participate in [Medicaid], if a state chooses to do so, it must comply with federal statutory and regulatory requirements” for mandatory services.¹²⁰ Coverage for outpatient prescription drugs is an optional service, but as with all optional Medicaid programs, “once a state elects to provide an optional service, that service becomes part of the state Medicaid plan and is subject to the requirements

113. 42 U.S.C. § 1395w-102(e) (Supp. IV 2004); see also MAPRx Letter, *supra* note 104 (stating that “Medicare regulations are overly stringent. They exclude Part D coverage of medications—no matter how medically necessary—when they are prescribed for uses that are not listed on the U.S. Food and Drug Administration (FDA) label or supported by a citation in one of three specific medical compendia.”).

114. THE HENRY J. KAISER FAMILY FOUND., MEDICARE: A PRIMER 16 (2008), available at www.kff.org/medicare/upload/7615-02.pdf (last visited Jan. 3, 2009).

115. FURROW ET AL., *supra* note 93, at 782.

116. *Id.* at 783.

117. *Id.* at 782.

118. THE HENRY J. KAISER FAMILY FOUND., MEDICARE: A PRIMER 16 (2008), available at www.kff.org/medicare/upload/7615-02.pdf (last visited Jan. 3, 2009).

119. See 42 U.S.C. § 1396 (2000 & Supp. IV 2004); see also *Edmonds v. Levine*, 417 F. Supp. 2d 1323, 1326 (S.D. Fla. 2006).

120. *Edmonds*, 417 F. Supp. 2d at 1326; 42 U.S.C. § 1396a (2000 & Supp. IV 2004).

of federal law.”¹²¹ All states currently offer Medicaid prescription drug benefits.¹²²

Medicaid covers “medically accepted indication[s]” of “any use for a covered outpatient drug.”¹²³ “Medically accepted” is defined as a use which is approved by the FDA, or a non-FDA approved use which is supported by citation in one of three approved compendia.¹²⁴ In addition to subjecting a covered outpatient drug to prior authorization, there are four other ways a state Medicaid agency may exclude drugs outside of this definition from coverage:

1. Prescribed use is not for a medically accepted indication (either FDA approved or supported by citation in a compendium);
2. Drug is listed as a restricted drug in § 1396r-8(d)(2) or is subsequently determined by the Secretary of HHS by regulation to be subject to clinical abuse or inappropriate use;
3. Drug is subject to restriction pursuant to an agreement between the state and drug manufacturer; or
4. Drug has been excluded by a state-established formulary, which is a list of Medicaid eligible drugs for which the state will provide reimbursement when prescribed for medically accepted indications.¹²⁵

If a state decides to require prior authorization of an excluded drug, there are two means by which it can do so: pursuant to the state’s formulary or as authorized directly by the Medicaid Act.¹²⁶ Under the former option, if a doctor wishes to prescribe a drug that has been excluded under the state’s formulary, he or she can “contact the state, convey medical information specific to the patient, and perhaps obtain an *exception* to the exclusion for the requested drug (and thus obtain reimbursement for that drug).”¹²⁷ However, the doctor’s request can be denied by the state, making the state “the final authority over coverage of non-formulary drugs.”¹²⁸ Thus, states

121. *Doe v. Chiles*, 136 F.3d 709, 714 (11th Cir. 1998); see also 42 U.S.C. § 1396d(a)(12) (2000 & Supp IV 2004).

122. Dawn M. Gencarelli, *Medicaid Prescription Drug Coverage: State Efforts to Control Costs*, NAT’L HEALTH POL’Y F. ISSUE BRIEF NO. 790 (George Washington U., Wash. D.C.), May 10, 2003, at 3, available at http://nhpf.ags.com/pdfs_ib/IB790_StateRx_5-10-03.pdf (last visited Jan. 3, 2009).

123. 42 U.S.C. §§ 1396r-8(k)(6), (k)(2)(A) (2000).

124. 42 U.S.C. § 1396r-8(k)(6) (2000).

125. 42 U.S.C. § 1396r-8(d)(1)(B)(i)-(iv) (2000).

126. 42 U.S.C. § 1396r-8(d)(4)-(5) (2000).

127. *Edmonds v. Levine*, 417 F. Supp. 2d 1323, 1328 (S.D. Fla. 2006) (emphasis added).

128. *Id.*

can restrict the coverage of off-label drug uses to a greater degree than the Medicaid Act does alone.

The second type of prior authorization program was established by the Medicaid Act itself. Under this approach, when a doctor wishes to prescribe a drug that requires prior authorization, he or she must first contact the state pharmacist who then shares information with the doctor about possible alternatives that are equally effective but less costly.¹²⁹ Ultimately, however, the doctor's right to prescribe the original drug is guaranteed one hundred percent as long as he or she calls the state pharmacist.¹³⁰ Just having this added means of communicating equally effective and less costly drug remedies has produced "substantial cost savings for organizations purchasing large volumes of drugs."¹³¹ In this sense, prior authorization cannot be used to deny coverage of off-label uses that are approved under the Medicaid Act, as can be done in situations where prior authorization is tied to a state formulary.¹³² Rather, a state can only condition coverage on the doctor making the call to the state pharmacist.¹³³

The issue of whether a state can deny coverage under its Medicaid laws after establishing a certain type of prior approval procedure was recently litigated in Florida. In *Edmonds v. Levine*, the refusal of Florida's Medicaid agency to "cover off-label drugs cited in any of the drug compendia unless they are supported by double-blind, placebo-controlled, randomized clinical trials" was found to violate the Medicaid Act.¹³⁴ Florida had not established a drug formulary. Therefore, prior authorization procedures were based on the Medicaid Act, which does not allow for outright denial of a covered drug.¹³⁵ In this case, the Florida Medicaid agency tried to condition approval on results similar to what would be required for FDA approval, which was more than the state is allowed to do.¹³⁶

Under the Medicaid Act, a state may limit drugs which would normally be covered under Medicaid by excluding the drugs from the state formulary, as long as the excluded drug "does not have a significant, clinically meaningful therapeutic advantage in terms of safety, effectiveness, or

129. *Id.* at 1329.

130. *Id.*

131. *Id.*; see also *Pharm. Research and Mfrs. of America v. Meadows*, 304 F.3d 1197, 1198 (11th Cir. 2002) (discussing Florida's drug formulary and the impact of requiring physicians to call the state pharmacist, concluding that "[d]uring the first three months of the program, approximately 55 percent of all...calls...resulted in a change of the prescription to a drug on the preferred drug list.").

132. *Edmonds*, 417 F. Supp. 2d at 1329.

133. *Id.*

134. *Id.* at 1336.

135. *Id.* at 1329.

136. See *Weeks*, *supra* note 1, at 655 (discussing FDA clinical trial requirements).

clinical outcome' over other drugs included in the formulary."¹³⁷ However, if a state does not establish a formulary, coverage defaults to the Medicaid Act, which covers all FDA-approved indications and those which are included in one of the three compendia.¹³⁸ This seems to focus mostly on the best remedy for the patient, while still giving the states relative autonomy regarding what they will choose to cover based on their individual budgets and plan structures.

3. Socialized Medicine in the United Kingdom

Healthcare in the U.K. is publicly financed through "non-earmarked general taxation and national insurance contributions" which are allocated by the National Health Service (NHS).¹³⁹ These funding sources cover most healthcare services at the point of delivery; prescription drugs are covered by flat-rate charges, "although the majority of users qualify for exemption from prescription drug charges."¹⁴⁰ In England, general practices (GPs) provide primary healthcare services under contracts between the independent practitioners and the NHS.¹⁴¹ GPs are paid on a capitation basis and this income is supplemented by a Basic Practice Allowance.¹⁴² Hospital services are provided through NHS Trusts, which employ the entire staff of the hospital.¹⁴³

Traditionally, doctors' decisions in the U.K. have remained largely free from government control, but the establishment of the National Institute for Clinical Excellence (NICE) in 1999 has led to increased regulation of clinical practices.¹⁴⁴ The aim of NICE is to identify the practices that make the best use of resources and how those resources can be rationed in the healthcare system.¹⁴⁵ NICE advises on the cost-effective use of NHS resources and establishes clinical guidelines and a framework for clinical governance.¹⁴⁶ NICE has faced resistance from the pharmaceutical

137. *Edmonds*, 417 F. Supp. 2d at 1328 (quoting 42 U.S.C. § 1396r-8(d)(4)(C) (2000)).

138. See *Edmonds*, 417 F. Supp. 2d at 1327-28 (discussing how inclusion of a drug in a state formulary is the only way a state can unilaterally exclude an indication which would otherwise be considered medically accepted under federal law).

139. Dillon et al., *supra* note 56, at 141; National Health Service, About the NHS, at www.nhs.uk/aboutnhs/Pages/About.aspx (last visited Jan. 3, 2009).

140. Dillion et al., *supra* note 56, at 141.

141. *Id.*

142. *Id.*

143. *Id.*

144. *Id.* at 142.

145. Dillon et al., *supra* note 56, at 138.

146. Tom Walley et al., *An Integrated National Pharmaceutical Policy for the United Kingdom?*, 321 BRIT. MED. J. 1523, 1524 (2000).

industry, which claims that NICE decisions undermine “the continued existence of the pharmaceutical industry in the United Kingdom.”¹⁴⁷

A significant issue in any universal healthcare system is how to keep coverage high and costs low, as there is only so much money to cover everyone. The U.K. provides a model of this struggle with respect to prescription drugs because the cost of prescription drugs has increased, while widespread exemptions from drug co-payments have effectively assigned the burden of this additional cost to the NHS.¹⁴⁸ In the U.K., prescription drugs are covered by a fixed co-payment of around £6.00 per prescription, but many people are exempt from this charge.¹⁴⁹ A significant portion of the NHS budget is therefore spent on pharmaceuticals, and notable increases in the amount that NHS spends on pharmaceuticals relative to other budget items has raised concern in recent years.¹⁵⁰ As a result, commentators in the U.K. have called for analysis of cost-effectiveness before NHS decides whether or not to pay for a new drug.¹⁵¹

Just like in the U.S., drug approval in the U.K. is based on proof of the drug’s safety and efficacy.¹⁵² Subsequent to this approval, NICE recommends whether a drug should be publicly funded based on both clinical effectiveness *and* cost-effectiveness, taking into consideration how the drug will impact a patient’s quality of care compared with the cost of the drug relative to available alternatives.¹⁵³ The guidance promulgated by NICE to NHS is meant to standardize healthcare across the country and end problems such as “rationing by postcode”, that is, “uneven access in geographical areas”.¹⁵⁴ Once NICE decides to recommend a medicine, “the NHS is legally obliged to fund and resource” that medicine.¹⁵⁵

The role of NICE in approving drugs and devices reflects the onset of new data requirements that have arisen generally in European countries as a means of efficient healthcare delivery (including effectiveness, cost-

147. *Id.* at 1523.

148. EUROPEAN OBSERVATORY ON HEALTH CARE SYSTEMS, HEALTH CARE SYSTEMS IN TRANSITION: UNITED KINGDOM 82 (1999), available at www.euro.who.int/document/e68283.pdf (last visited Jan. 3 2009) [hereinafter EUROPEAN OBSERVATORY REPORT].

149. Dillon et al., *supra* note 56, at 142.

150. *Id.* NHS allocates over twelve percent of its annual budget to cover this difference. *Id.*

151. *Id.* at 143.

152. *Id.* at 152.

153. *Id.*

154. Dillon et al., *supra* note 56, at 138; National Health Service, National Institute for Health and Clinical Excellence, About Technology Appraisals, at www.nice.org.uk/aboutnice/whatwedo/abouttechnologyappraisals/about_technology_appraisals.jsp (last visited Jan. 3, 2009) [hereinafter NICE Appraisals].

155. NICE Appraisals, *supra* note 154.

effectiveness and budgetary impact).¹⁵⁶ This trend is further demonstrated by the fact that there is a “Limited List” in the U.K.—a list of drugs that have been excluded from NHS prescribing on the grounds of “poor therapeutic value or excessive cost.”¹⁵⁷ Taking into account both clinical and cost-effectiveness could likely lead to the exclusion of off-label treatments that are found lacking in such a cross-analysis.

4. Mandatory Health Insurance in Switzerland

Some have suggested that the Swiss system of universal healthcare would be the best model for the United States to follow when structuring its own universal healthcare system.¹⁵⁸ Switzerland is a democratic, capitalist country that is not a member of the European Union, and since 1994 it has had a system of healthcare that requires every citizen have health insurance.¹⁵⁹ For those who can afford it, the government has set a uniform flat premium rate at the equivalent of \$750 for individual basic comprehensive coverage, and for those who cannot afford to pay for the premium, the government subsidizes the cost.¹⁶⁰ Swiss law prohibits insurance companies from making a profit on basic insurance coverage, but allows more competition for supplemental insurance, such as dental coverage.¹⁶¹

The societal view in Switzerland is that everyone has a right to high quality healthcare, just as one would have a right to education or a legal defense in the United States.¹⁶² For this right, citizens of Switzerland pay more for their health insurance than citizens of any other European country.¹⁶³ But while Swiss citizens commonly protest the rising cost of premiums, they still spend substantially less on healthcare than Americans do, almost no one ever goes bankrupt due to medical bills, and everyone,

156. See Mark J. C. Nuijten & Jozsef Kosa, *Pricing of Pharmaceuticals: Assessing the Pricing Potential by a Pricing Matrix Model*, 2 EUR. J. HEALTH ECON. 110, 110 (2004).

157. EUROPEAN OBSERVATORY REPORT, *supra* note 148, at 82.

158. See Julie Rovner, *In Switzerland, A Health Care Model For America?*, NAT’L. PUB. RADIO, ALL THINGS CONSIDERED, July 31, 2008, at www.npr.org/templates/story/story.php?storyId=92106731 (last visited Jan. 3, 2009); see also Couchepin Interview, *supra* note 85 (interviewer stating that the Swiss system has been looked to as a model for an American universal healthcare system since Switzerland has a market-driven economy that is similar to the U.S. economy.)

159. Couchepin Interview, *supra* note 85.

160. Frontline, *Five Capitalist Democracies & How They Do It*, at www.pbs.org/wgbh/pages/frontline/sickaroundtheworld/countries/ (last visited Jan. 3, 2009) [hereinafter Frontline Report].

161. *Id.*

162. See Couchepin Interview, *supra* note 85.

163. *Id.*

regardless of socio-economic status, receives the same quality of care.¹⁶⁴ However, healthcare costs in Switzerland have increased substantially since 1994, due in part to the fact that people tend to use healthcare services more when health coverage becomes compulsory in an effort to get their money's worth, which has caused Switzerland's president to question whether mandated universal coverage was the appropriate path to take towards universal healthcare.¹⁶⁵

While the standard price of medical services is negotiated between the providers and the insurers, the price of prescription drugs is set by the government.¹⁶⁶ To keep costs as low as possible, the Swiss government requires people to take generics whenever possible. If they choose non-generic drugs, they have to pay at least part of the higher additional cost on their own.¹⁶⁷ For prescription drugs, the government looks to other European countries and sets prices after considering the average prices of the most commonly used drugs.¹⁶⁸ This approach is used despite the influence of powerful Swiss pharmaceutical companies, who have accepted the mandate of using generics.¹⁶⁹ Perhaps this is because Swiss citizens still pay more for drugs than most other Europeans, and the Swiss government is admittedly open to paying more for "new drugs with huge therapeutic advantage" in an effort to "support innovation and not to support profits in [and of themselves]."¹⁷⁰

This approach to prescription drugs may be why Switzerland is a country where off-label and unlicensed drug use is common, particularly in pediatric wards.¹⁷¹ As discussed *supra*, SwissMedic has established that it will extend the patent protection for any drug where the manufacturer voluntarily endeavors to research uses of that drug in children, so that the drug may no longer have to be prescribed off-label.¹⁷² In Switzerland, the healthcare system is designed to provide all citizens with high-quality, comprehensive care,¹⁷³ and this underlying aim explains, in part, the government's

164. *Id.*; see generally USA TODAY, THE HENRY J. KAISER FAMILY FOUNDATION & HARVARD SCHOOL OF PUBLIC HEALTH, HEALTH CARE COSTS SURVEY (2005) (summarizing findings of how health care costs have impacted access to care, with special attention to members of lower socio-economic classes who tend to avoid care for chronic conditions due to cost).

165. Couchepin Interview, *supra* note 85.

166. *Id.*; see also Frontline Report, *supra* note 160.

167. Couchepin Interview, *supra* note 85.

168. *Id.*

169. *Id.*

170. *Id.*

171. See Di Paolo et al., *supra* note 70, at 218, 220.

172. *Id.*; see also *supra* note 76 and accompanying text.

173. SWISS CONFEDERATION, FED. DEP'T OF HOME AFF., FED. OFFICE OF PUB. HEALTH, THE COMPULSORY HEALTH INSURANCE IN SWITZERLAND: YOUR QUESTIONS, OUR ANSWERS 4 (2008), at

openness to paying higher prices for drugs and providing incentives for continued research of unapproved uses.

Not all drugs are covered *carte-blanche* in Switzerland, however. Under the basic comprehensive insurance required of all citizens, only those drugs that are prescribed by a doctor and included in the "List of pharmaceutical specialties" are covered.¹⁷⁴ This list is compiled by the Swiss Federal Office of Public Health (FOPH) and currently includes roughly 2,400 medications, although the list is frequently revised "in light of medical progress."¹⁷⁵ In addition to the drugs included on the "List of pharmaceutical specialties," pharmacists are permitted to dispense equivalent generic drugs unless the prescribing physician has specifically ordered the brand name drug for medical reasons.¹⁷⁶

More generally, FOPH states that "[t]he basic assumption concerning medical benefits is that they comply with legal provisions relative to effectiveness, appropriateness and efficiency."¹⁷⁷ FOPH allows denials of coverage to be challenged before an expert commission, but the Federal Department of Home Affairs retains the authority to make the final decisions with respect to such appeals.¹⁷⁸

The Swiss government remains open to working with the pharmaceutical companies to approve new uses for drugs, while still understanding the need to protect patient welfare and keep costs manageable. By limiting the market's influence over the off-label use of pharmaceuticals by strictly prohibiting the promotion of off-label uses, the Swiss system focuses its efforts on patient safety as part of fulfilling the goal of providing all citizens high-quality comprehensive care. The government's control over drug prices and the inclusion of a limited number of drugs under the basic health insurance package adds to the concern about patient safety the additional concern of cost-effectiveness. The Swiss approach to prescription drug is substantially similar to that of the U.K., albeit structured in a slightly different way, and thus outcomes for off-label drugs would also likely be similar.

IV. PROSPECTS FOR UNIVERSAL HEALTHCARE IN THE UNITED STATES

Proposals for American universal healthcare have become one of the most discussed topics in healthcare over the past few years. The 2008

www.bag.admin.ch/themen/krankenversicherung/00263/00264/index.html?lang=en (follow "Your questions, our answers" hyperlink) (last visited Jan. 3, 2009).

174. *Id.* at 7.

175. *Id.*

176. *Id.*

177. Federal Office of Public Health, 1. Medical Benefits, at www.bag.admin.ch/themen/krankenversicherung/00263/00264/02418/index.html?lang=en (last visited Jan. 3, 2009).

178. *Id.*

presidential election made the prospect of universal healthcare in America more tangible than ever before. All three frontrunners for the 2008 Democratic presidential nomination touted their own versions of a universal healthcare regime, and although the candidates borrowed ideas from each other, each also introduced his or her own unique elements.¹⁷⁹ Any future universal healthcare regime will undoubtedly embody a mixture of many of the elements introduced in these plans.

A critical first step towards establishing any universal healthcare regime is to determine who will pay for it. Unlike some European plans where coverage is completely funded by the government via tax revenue,¹⁸⁰ most proposals for American universal healthcare seek to modify the current American health insurance system, in which some people are covered by government-funded medical coverage while others are covered by private insurance.¹⁸¹ Most proposals also rely on the existing Medicare and Medicaid programs, but seek to strengthen federal and state partnerships for these programs,¹⁸² or mandate that all children and young people are covered through expansion of SCHIP and Medicaid.¹⁸³ No matter how the coverage plans are structured, the proposals contain other common elements, including tax credits to individuals who cannot afford premiums and co-pays but who do not qualify for Medicaid,¹⁸⁴ as well as tax credits to businesses so that they may provide comprehensive and “meaningful

179. Obama for America, Barack Obama’s Plan for a Healthy America: Lowering Health Care Costs and Ensuring Affordable, High-Quality Health Care for All, available at www.barackobama.com/pdf/HealthPlanFull.pdf (last visited Jan. 3, 2009) [hereinafter Obama Plan]; Hillary for President, American Health Choices Plan: Quality, Affordable Health Care for Every American, available at www.hillaryclinton.com/feature/healthcareplan/americanhealthchoicesplan.pdf (last visited Jan. 3, 2009) [hereinafter Clinton Plan]; John Edwards ‘08, Universal Health Care through Shared Responsibility, at www.johnedwards.com/about/issues/health-care-overview.pdf (last visited Jan. 3, 2009) [hereinafter Edwards Plan].

180. See, e.g., Interview by Frontline with Nigel Hawkes, Health Editor for *The Times* of London (Nov. 1, 2007), at www.pbs.org/wgbh/pages/frontline/sickaroundtheworld/interviews/hawkes.html (last visited Jan. 3, 2009) (discussing the system of socialized medicine in the U.K.).

181. See Obama Plan, *supra* note 179, at Quality, Affordable & Portable Health Coverage for All; see generally Clinton Plan, *supra* note 179, at Executive Summary; see generally Edwards Plan, *supra* note 179, at Universal Coverage Through Shared Responsibility.

182. Edwards Plan, *supra* note 179, at Universal Coverage Through Shared Responsibility.

183. Obama Plan, *supra* note 179, at Quality, Affordable & Portable Health Coverage for All.

184. Obama Plan, *supra* note 179, at Quality, Affordable & Portable Health Coverage for All; Edwards Plan, *supra* note 179, at Universal Coverage Through Shared Responsibility; Clinton Plan, *supra* note 179, at Executive Summary.

coverage" to employees.¹⁸⁵ Tax-credits may also be used to offset the cost of catastrophic illnesses in the aging baby boomer population.¹⁸⁶

Certain proposals have created institutions that would reform the private insurance market by scrutinizing plans to ensure that they are comparable to the public plan,¹⁸⁷ or by creating purchasing pools which would allow for the negotiation of low premiums based on economies of scale.¹⁸⁸ This proposed scrutiny of the private insurance market furthers an important aim of most universal healthcare coverage proposals: cutting costs to make insurance premiums fair and affordable for everyone. How much people are able to pay is considered when determining what people will have to pay, such as by limiting premiums to a certain percentage of the beneficiary's income.¹⁸⁹ At the same time, these plans also focus on providing high quality, effectiveness-tested health care, with some form of a national, independent institution to ensure quality and effectiveness, another element common to most universal healthcare proposals.¹⁹⁰ The purpose of these institutions would be two-fold: first, to ensure the highest quality of care, and second, to make sure that the procedures, drugs, and devices in current use are cost-efficient. To that end, most proposals promote research and the use of generic drugs,¹⁹¹ and one proposal even goes as far as to encourage the re-importation of drugs from countries where they are less costly.¹⁹² Two suggested plans suggest changing the MMA so that Medicare would be able to negotiate drug prices with pharmaceutical companies, another effort to lower drug prices.¹⁹³ Reducing cost would

185. Obama Plan, *supra* note 179, at Quality, Affordable & Portable Health Coverage for All; Edwards Plan, *supra* note 179, at Universal Coverage Through Shared Responsibility; Clinton Plan, *supra* note 179, at Executive Summary.

186. Clinton Plan, *supra* note 179, at Executive Summary.

187. Obama Plan, *supra* note 179, at Quality, Affordable & Portable Health Coverage for All.

188. Edwards Plan, *supra* note 179, at Universal Coverage Through Shared Responsibility.

189. Clinton Plan, *supra* note 179, at Executive Summary.

190. Obama Plan, *supra* note 179, at Modernizing the U.S. Health Care System to Lower Costs & Improve Quality; Clinton Plan, *supra* note 179, at Detailed Plan: Eliminate Insurance Discrimination, Improve Quality, and Rein-in Costs; Edwards Plan, *supra* note 179, at Affordable and Accountable Health Care.

191. Edwards Plan, *supra* note 179, at Affordable and Accountable Health Care; Obama Plan, *supra* note 179, at Modernizing the U.S. Health Care System to Lower Costs & Improve Quality.

192. Obama Plan, *supra* note 179, at Modernizing the U.S. Health Care System to Lower Costs & Improve Quality.

193. Obama Plan, *supra* note 179, at Modernizing the U.S. Health Care System to Lower Costs & Improve Quality; Clinton Plan, *supra* note 179, at Fiscal Responsibility that Honors Priorities.

clearly play a central role in any American universal healthcare program, as it currently does in the British and Swiss systems.

V. ANALYSIS

It is no surprise that cost is a critical factor in determining how off-label drug uses are covered by government-funded insurance programs. The British model demonstrates how important rationing is when working with a limited supply of resources. In the U.S., total spending on Medicare after the implementation of the Part D Prescription Drug Benefit was expected to increase from \$342 billion in 2005 to \$417.6 billion in 2006, while continuing to grow in 2007.¹⁹⁴ Spending on Medicaid, despite slowing around 2005-2006, is expected to “grow 8.1 percent a year on average from 2008 through 2016”, starting from a 2006 base of \$313.5 billion.¹⁹⁵ Further, spending on prescription drugs is expected to total \$497.5 billion by 2016.¹⁹⁶

At the same time, the Swiss experience demonstrates that when healthcare is compulsory for a population, an incentive to increase consumption of healthcare services is created because people feel compelled to get their money’s worth, which leads, in turn, to an overall increase in healthcare expenditures.¹⁹⁷ The creation of this incentive is one of the ironies of universal healthcare—it has the potential to increase costs even while the government that funds or subsidizes the system works to contain costs. The theory of “moral hazard” is commonly used by opponents of universal healthcare,¹⁹⁸ but despite any negative consequences that result from the structure of its healthcare system, Switzerland still spends far less per capita on healthcare than the U.S. does.¹⁹⁹ The U.S. spent \$6,714 per capita in total spending on healthcare in 2006, the most of any country, while comparatively, Switzerland spent

194. *Health Care Spending to Double by 2016, Despite Slight Slowdown in 2006*, CMS Says, 12 Health Care Daily Rep. (BNA) No. 34, at Lead Report (Feb. 21, 2007).

195. *Id.*

196. *Id.*

197. Couchepin Interview, *supra* note 85.

198. See generally Malcolm Gladwell, *The Moral-Hazard Myth: The Bad Idea Behind Our Failed Health-Care System*, NEW YORKER, Aug. 29, 2005, at www.newyorker.com/archive/2005/08/29/050829fa_fact?currentPage=all (last visited Jan. 3, 2009) (describing the moral hazard theory as “a powerful impediment to the expansion of health insurance.”).

199. See Organisation for Economic Co-operation and Development, OECD Health Data 2008 - Frequently Requested Data, at Total health expenditure per capita, US\$ purchasing power parity, June 2008, at www.oecd.org/document/16/0,3343,en_2649_34631_2085200_1_1_1_1,00.html (last visited Jan. 3, 2009) [hereinafter OECD Health Data]; see also Couchepin Interview, *supra* note 85.

\$4,311 per capita, and the U.K. spent just \$2,760 per capita!²⁰⁰ Despite much higher spending, however, the U.S. still ranks last in many key quality indicators among other industrialized countries.²⁰¹

Most proposed universal healthcare plans aim to provide healthcare coverage to all citizens while simultaneously reducing healthcare costs. These goals are important especially with regard to the pharmaceutical industry, as reducing pharmaceutical costs is a vital step toward reducing overall spending. An element common to both the proposed American plans and the Swiss system is a focus on using generic drugs. Additionally, many proposed American plans demand that the Secretary of HHS be able to negotiate Medicare drug prices with the pharmaceutical industry. This could be a way to implement some government influence over drug prices without taking away all American capitalist spirit by allowing the government to control prices directly, as is the case in Switzerland. By focusing on generic drugs and allowing the Secretary of HHS to negotiate with the pharmaceutical companies, pharmaceutical manufacturers will have a stronger incentive to keep costs low so they can effectively compete with generic drug companies and generate profits in the face of likely lower negotiated drug prices. These changes could significantly impact the pharmaceutical industry's willingness to comply with federal regulations concerning off-label promotion. Given that there is a fair amount of disregard for such restrictions now, due to the high cost of post-market testing and after-market approval cost, as well as the short amount of time to enjoy patent protection, new measures which focus on generics could give pharmaceutical companies more incentive to get as much return on their investments as possible.

In addition to spending substantially more on healthcare as a whole, the United States also spent almost twice as much as Switzerland on pharmaceuticals in 2005, and, once again, more than any other organisation for Economic Co-operation and Development (OECD) country.²⁰² While expenditure on pharmaceuticals as a percentage of total healthcare spending is substantially lower in the U.S. than it is in other countries, this is only because the U.S. spends considerably more on

200. OECD Health Data, *supra* note 199.

201. *Despite Spending More, U.S. Ranks Last in Several Key Health Indicators, Study Finds*, 12 Health Care Daily Rep. (BNA) No. 93, at Lead Report (May 15, 2007).

202. OECD Health Data, *supra* note 199. The Organisation for Economic Co-operation and Development (OECD) is a multinational organization of 30 democratic, capitalist countries which coordinates efforts to sustain economic growth among its members. The United States, Switzerland and the United Kingdom are all members of the OECD. See Organisation for Economic Co-operation and Development, About OECD, at http://www.oecd.org/pages/0,3417,en_36734052_36734103_1_1_1_1_1,00.html (last visited Jan. 6, 2009).

healthcare overall.²⁰³ It appears that the high rate of spending on drugs in the U.S. correlates to a higher rate of per capita spending on healthcare, therefore implying that in order to cut the overall cost of healthcare, spending on drugs will also need to be cut. As the *Layzer* case demonstrates, the cost of drugs used off-label can be substantial, and the fact that Ms. Layzer's drugs are not covered by Medicare Part D could be an indication that the idea already exists in the United States that some costs are just not justified.²⁰⁴

Further support that this idea is not a new concept in the U.S. is found in the fact that most American universal healthcare proposals would set up an independent national agency or institute to ensure effectiveness and quality, similar to the role of NICE in the U.K. While the U.K. model demonstrates that an agency that focuses on comparative effectiveness of alternative treatments could have the effect in the U.S. of shifting the off-label question away from whether an off-label use is safe and effective to whether such a use is too costly, this common thread between all three candidate proposals suggests that a centralized agency similar to NICE is likely to become a fixture of any American universal healthcare system, along with the accompanying focus on cost-effectiveness.

Additionally, under the healthcare structure in Switzerland, insurance companies are forced to compete with each other because the government believes that, in a strong capitalist society, "if there is competition between the health insurance companies, there will be a certain control among themselves; they will denounce the excesses of the others, . . . and also they will try to provide better services, and so you can compare" the plans offered by each company.²⁰⁵ The Swiss government directly rejects a single payer insurance system because it believes in the capitalist ideal that competition improves quality.²⁰⁶ One proposal for an American universal system would prefer to pool purchasing power for drugs, similar to the way PDPs work under Medicare Part D.²⁰⁷ As discussed *supra*, the fact that PDPs are provided by private insurance companies that make bids to HHS seems to be related to a more limited coverage rate of off-label drugs.²⁰⁸ While pooling purchasing power in such a way may lead to improved economies

203. *Id.* at Pharmaceutical expenditure, % expenditure on health.

204. Complaint at 1-4, *Judith M. Layzer & Ray J. Fischer v. Michael O. Leavitt*, No. 07-CV-11339 (S.D.N.Y. Dec. 18, 2007).

205. Couchepin Interview, *supra* note 85.

206. *Id.*

207. Edwards Plan, *supra* note 179, at Universal Coverage Through Shared Responsibility; see FURROW ET AL., *supra* note 93, at 782, 784 (discussing how the country is split into thirty-four PDP regions, where competing PDPs bid to cover the region; also, PDPs have the ability to negotiate with drug manufacturers over drug prices).

208. FURROW ET AL., *supra* note 93, at 782.

of scale, the Swiss system has established that competition creates better choices for consumers, an idea which would likely also imply a better selection of off-label drugs. By combining purchasing pools with stricter regulation of the pharmaceutical industry, the outcome would likely be a lower rate of coverage for off-label drug use.

VI. CONCLUSION

Current proposals for universal healthcare in the United States and European healthcare system models demonstrate that cost is and will continue to be a primary concern for healthcare policymakers. While quality remains an important consideration, universal healthcare remains a lesson in basic economics, where a scarce supply of resources must be rationed among an endless demand for services.²⁰⁹ Both the British and Swiss healthcare models contain elements of cost-effectiveness, and both have definitive measures in place to help control the cost of drugs. This is not to suggest that cost is the only concern, however, since one of the primary issues with off-label use is whether the off-label use is well supported by clinical studies that would demonstrate that the product is safe. Despite the focus on cost-effectiveness, all models and proposals discussed designate quality of care as a primary goal. Therefore, even if off-label drugs may be better at treating certain problems or patient groups, the fact that the off-label use is essentially experimental may imply that expensive off-label drugs could be excluded from coverage on the grounds of both cost and safety.

Indeed, in the U.S., the Medicaid model seems to focus less on cost-effectiveness and more on being able to provide safe treatment to beneficiaries. However, Medicaid budgeting varies so much from state-to-state that it is hard to draw any firm conclusions about Medicaid decision-making across the country.²¹⁰ In contrast, the fact that Medicare Part D offers less coverage than Part B may reflect how the high level of prescription drug spending in the United States was considered when Congress determined whether the Secretary of HHS would have the ability to expand the compendia with peer-reviewed literature.

209. See R. Douglas Scott, II et al., *Applying Economic Principles to Health Care*, 7 EMERGING INFECTIOUS DISEASES (SPECIAL ISSUE) 282 (2001) (noting that "the basic problem addressed by economics is how to allocate limited resources among unlimited demands.").

210. See, e.g., The Henry J. Kaiser Family Found., *Medicaid Cost Containment Actions Taken by States, FY 2008*, at www.statehealthfacts.org/comparetable.jsp?ind=187&cat=4 (last visited Jan. 3, 2009); see also The Henry J. Kaiser Family Found., *Positive Medicaid Policy Actions Taken by States, FY 2008*, at www.statehealthfacts.org/comparetable.jsp?ind=190&cat=4 (last visited Jan. 3, 2009) (both tables demonstrate the variety of ways that states have constructed their Medicaid programs).

Ultimately, the FDA is unlikely to prohibit off-label use altogether. A complete prohibition would involve regulating the practice of doctors which the FDA has repeatedly said that it will not do. Unless there is a significant crackdown on off-label promotion, any restrictions on pharmaceutical companies' profits is likely to give those companies stronger incentives to promote off-label use as a means of recouping the significant capital that is invested in drug development. However, an important question that remains unanswered is how any potential universal healthcare system will cover such drugs. Under the proposed plans that allow people to retain their private insurance plans, and for the people that will remain covered by Medicare and Medicaid, coverage might not change much in the short-term—some off-label uses will continue to be covered as long as manufacturers can establish that such uses are safe. As time goes on, however, and financial support for Medicare and Medicaid strains to support everyone covered by the two programs, it is quite possible that the determination of coverage for an off-label use will depend on more than just whether that off-label use is safe. In the future, with respect to Medicare and Medicaid reimbursement, or in the context of a newly created national health care system, the debate over off-label drug use is likely to switch from whether an off-label use is safe to whether that use is cost-effective. As the debate shifts, the opinions of healthcare providers as to what is best for their patients may not change, but whether those opinions align with what payors are willing to cover may eventually shape a new debate—one in which the question is how much is too much to pay, no matter how great the benefits.

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