

The National Essential Medicines List in China and
What the United States Can Learn

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I. DEVELOPMENT OF AN INTERNATIONAL STANDARD FOR ESSENTIAL
MEDICINES LISTS

The World Health Organization (WHO) first developed the model essential medicines list in 1977 to assist developing and developed countries in allocating limited healthcare resources.¹ The WHO defines essential medicines as being “those that satisfy the priority health care needs of the population.”² The model essential medicines list was born out of a request from the World Health Assembly to help member states achieve the mutually exclusive goal of greater access to care and cost containment.³

The initial list contained 205 medications⁴ that were considered absolutely vital to meeting the basic healthcare needs of the population.⁵ Although the list has evolved over time, the model has remained largely unchanged in selecting the types of drugs to be included on the list.⁶ The

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1. Richard Laing et al., *25 Years of the WHO Essential Medicines Lists: Progress and Challenges*, 361 LANCET 1723, 1723 (2003); see also, Hans V. Hogerzeil, *The Concept of Essential Medicines: Lessons for Rich Countries*, 329 BMJ 1169, 1169 (2004) (the first *Model List of Essential Medicines* was published by the World Health Organization in 1977, and the list is revised every two years).

2. *Essential Medicines*, WORLD HEALTH ORGANIZATION, http://www.who.int/medicines/services/essmedicines_def/en/index.html (last visited February 12, 2012).

3. Laing, *supra* note 1, at 1723.

4. *Id.* at 1724.

5. Michael R. Reich, *Essential Drugs: Economics and Politics in International Health*, 8 HEALTH POL'Y 39, 40 (1987).

6. Laing, *supra* note 1, at 1724.

list has grown in number to include over 300 medications.⁷ Currently, over 150 countries have adopted national essential drug lists.⁸

The ultimate goal of the essential drug list was to address the growing gap between the medical needs of the population and what essential drugs those countries were willing and able to provide.⁹ Specifically, the national essential medicine lists were designed to balance the competing needs of efficacy, safety, and cost.¹⁰ The list also encourages other reforms, such as reducing trade impediments, improving efficient distribution of the necessary medications, and encouraging more public funding of the essential drugs on the list.¹¹

China¹² and the United States¹³ have both implemented different forms of an essential medicines list. China developed a more substantial national list¹⁴ while the U.S. has delegated the development of the lists to the individual states to be used in Medicaid pharmaceutical procurement.¹⁵ China's system, while imperfect, provides a reasonable template for the

7. See WORLD HEALTH ORGANIZATION, WHO MODEL LIST OF ESSENTIAL MEDICINES 17th List (March 2011), available at <http://www.who.int/medicines/publications/essentialmedicines/en/index.html>; see also WORLD HEALTH ORGANIZATION, WHO MODEL LIST OF ESSENTIAL MEDICINES FOR CHILDREN 3RD LIST (March 2011), available at <http://www.who.int/medicines/publications/essentialmedicines/en/index.html> (the World Health Organization also developed an essential drug list that deals exclusively with children and their unique medical requirements. This published list is in its third edition and includes medications that are considered to be essential for the health and wellbeing of children).

8. Pieter Stolk, Marjolein JC Willemsen, & Hubert GM Leufkens, "Rare Essentials": *Drugs for Rare Diseases as Essential Medicines*, 84 BULL. OF THE WORLD HEALTH ORG. 745, 745 (2006); see also Laing, *supra* note 1, at 1723 (the number of countries has varied but consistently remained above 150).

9. Reich, *supra* note 5, at 40.

10. Hogerzeil, *supra* note 1, at 1169.

11. Stephen P. Marks, *Access to Essential Medicines as a Component of the Right to Health*, HEALTH: A HUMAN RIGHTS PERSPECTIVE 85, available at http://www.swisshumanrightsbook.com/SHRB/shrb_03_files/04_453_Marks.pdf.

12. Xiaodong Guan, et al, *An Analysis of China's National Essential Medicines Policy*, 32 JOURNAL OF PUBLIC HEALTH POLICY 305, 306 (2011).

13. Timothy Millar, et al, *Applying the Essential Medicines Concept to US Preferred Drug Lists*, 101 AMERICAN JOURNAL OF PUBLIC HEALTH 1444, 1444 (2011).

14. Guan, *supra* note 12, at 306.

15. Millar, *supra* note 13, at 1444.

U.S. to develop and integrate an essential medicines list for the purposes of cost containment and greater access to necessary medicine.

The paper will first discuss China's essential medicines list, its implementation, and benefits and concerns. Next, it will provide an overview of the U.S. system, its use at the state level in Medicaid, and its inefficiencies. Finally, this paper will discuss the challenges and opposition to the implementation of a national essential medicines list in the U.S.

II. THE ESSENTIAL DRUG LIST IN CHINA AND ITS INTEGRATION INTO NATIONAL HEALTHCARE POLICY

China first developed a national essential medicine list (NEML) in 1982, which included 278 Western medicines.¹⁶ The current list contains 307 different chemical varieties and provincial lists contain up to 200 additional medicines.¹⁷ The NEML is governed by several Chinese ministries, including the Ministry of Health (MOH), which has been tasked with developing and maintaining the list; the National Development and Reform Commission (NDRC) (formerly the State Commission of Development and Planning¹⁸), which is engaged in managing costs through price controls¹⁹; and the State Food and Drug Administration (SFDA), which engages in inspections of production facilities to guarantee safety.²⁰

16. Guan, *supra* note 12, at 306 (China began work on developing a NEML in 1979 and published the first NEML three years later).

17. *Id.* at 307 (the number of medicines on the list has fluctuated greatly, dropping from 2033 in 2004 to 307 in 2009); see also Wang Wenjie, *Perfecting the Essential Drug System Takes Time*, BEIJING REV. (March 12, 2010), http://www.bjreview.com/Cover_Story_Series_2010/2010-03/12/content_257598.htm.

18. Yingyao Chen & Stuart O. Schweitzer, *Issues in Drug Pricing, Reimbursement, and Access in China with References to Other Asian Pacific Regions*, 11 VALUE IN HEALTH S124, S125 (2008).

19. Qiang Sun et al, *Pharmaceutical Policy in China*, 27 HEALTH AFF. 1042, 1044 (2008) (the state mandates the mark-up at 15%; however, there is no significant oversight and realistic markups are most likely over 40%).

20. *Id.* at 1044 (the NDRC is engaged in issuing policies and setting maximum prices by allowing a standard mark-up on the average cost of production. Overall, approximately 60% of pharmaceutical products sold in China are governed by NDRC price controls).

State support for China's hospitals has fallen from approximately 60% in the 1980s to 8.3% in 2003.²¹ As state support for the healthcare system was reduced, hospitals were encouraged to develop new revenue stream.²² As a result, hospitals now subsidize clinical services with income derived from prescriptions, which motivates physicians to prescribe more expensive medications.²³ Physicians are also inclined to overprescribe, often prescribing multiple medications per clinic visit.²⁴

Hospitals also profit from the prescribing of higher priced medications and from the encouragement of physicians to prescribe these costly medications. Patients in China are more likely to fill their prescriptions in hospitals than patients in the U.S.²⁵ This is due to the patients' concern regarding the quality of medication available at retail pharmacies, the recommendation of the treating physician, convenience, and availability of prescription drugs at hospitals versus retail pharmacies.²⁶ In 2006, 41.5% of the hospital revenue was derived from pharmaceutical sales.²⁷

Another systemic issue in China is the distribution of pharmaceuticals. In 2009, the NDRC has implemented retail price controls on 2,349 different medical products.²⁸ Retail price controls are statutory maximum prices, which have effectively reduced retail prices by, on average, twelve

21. *Id.* at 1046.

22. *Id.*

23. Guan, *supra* note 12, at 308.

24. Lifang Dong et al, *Drug Prescribing Indicators in Village Health Clinics Across 10 Provinces of Western China*, 28 *FAMILY PRACTICE* 63, 65 (2011) (the rate at which physicians prescribe antibiotics is much higher than in other countries, suggesting that there is a general tendency to overprescribe); *see also* Guan, *supra* note 12, at 309 (“[s]eventy per cent of prescriptions contained antibiotics, making China one of the heaviest users of antibiotics”).

25. Sun, *supra* note 19, at 1046 (approximately four-fifths of all prescriptions filled in China are filled in retail pharmacies within the hospitals themselves).

26. *Id.* at 1047.

27. *Id.* at 1046.

28. Guan, *supra* note 12, at 311.

percent.²⁹ However, corruption within the system has allowed some drugs covered by the price controls to be rebranded as new medicines, which enables them to escape these controls.³⁰

The pharmaceutical industry's response to the price controls and the NEML has been problematic in the efforts to increase access to these drugs. First, because of price controls, pharmaceutical companies lack sufficient incentive to produce these drugs.³¹ As a result, there are chronic shortages of necessary medications in various markets across China.³² Second, pharmaceutical companies respond to price controls by rebranding these drugs so that they are not subjected to these price controls.³³ Again, this serves to limit the access patients have to affordable medicines.

China has enacted considerable health care reforms to address these issues.³⁴ They seek to find a solution for the high cost of medicine, as well as to extend medical insurance to over ninety percent of the population.³⁵ Currently, China maintains two separate systems for rural and urban healthcare, with urban participants receiving more benefits and coverage than those in rural areas.³⁶ In total, China is devoting 850 billion RMB (approximately \$124 billion USD) to revamping the healthcare system to increase access to necessary medical care and pharmaceuticals.³⁷

To address the issues of shortages of essential drugs on the market, in 2007 the SFDA designated ten pharmaceutical companies to manufacture

29. *Id.*

30. Sun, *supra* note 19, at 1044-1045.

31. *Id.* at 1045-1046.

32. *Id.* at 1046.

33. *Id.* at 1044-45.

34. Wenjie, *supra* note 17; *see also* Guan, *supra* note 12, at 306 (the three year plan will conclude in 2012; however, it will take some time to fully realize the impact the program had on expanding full healthcare coverage to the population).

35. Guan, *supra* note 12, at 306.

36. *Id.* at 313 (however, the rural cooperative scheme for reimbursement has not been implemented).

37. *Id.* at 306.

eighteen essential medicines to prevent future disruptions in production.³⁸ The SFDA has also invested energy and formulated policy to reduce the number of steps in the distribution chain to limit the markup that the end-using patient eventually pays.³⁹

III. USE OF ESSENTIAL DRUG LISTS IN THE UNITED STATES AND RELATED PROBLEMS

The U.S. developed the Medicaid system in 1965 to address providing health care for low-income citizens.⁴⁰ All fifty states manage their own Medicaid system.⁴¹ Each state's Medicaid system has developed a preferred drug list (PDL) to provide practitioners with guidance regarding effective prescribing.⁴²

Despite the use of a PDL within Medicaid, there are several problems associated with the lack of a national essential drug list in the U.S. First, the use of prescription medicine is likely to rise significantly as the population ages.⁴³ The elder age group is likely to consume more pharmaceutical products than other age groups due to health concerns commonly associated with aging.⁴⁴ This has led to an increase in pharmaceutical expenditures,⁴⁵ which is problematic because costs will most likely continue to rise as a result of the aging population and their pharmaceutical requirements. In addition, pharmaceutical costs remain

38. *Id.* at 308.

39. Sun, *supra* note 19, at 1044.

40. Millar, *supra* note 13, at 1444.

41. HEALTHCARE.GOV, <http://www.healthcare.gov/using-insurance/low-cost-care/medicaid/index.html> (last visited March 25, 2012).

42. Millar, *supra* note 13, at 1444.

43. Hogerzeil, *supra* note 1, at 1170; *see also* Andrew Ellner, *Rethinking Prescribing in the United States*, 327 *BMJ* 1397, 1397 (2003) (“the group aged over 65 is one of the fastest growing parts of the population”).

44. Ellner, *supra* note 43, at 1397.

45. Hogerzeil, *supra* note 1, at 1170 (pharmaceutical spending in the US increased 18% in 1999, 16% in 2000, and 17% in 2001).

high because of inefficient prescription methodologies, higher costs of new drugs, and increased quantities of drugs being prescribed.⁴⁶

Second, pharmacy benefits managers (PBMs) are largely responsible for creating the PDLs.⁴⁷ Undisclosed arrangements between the PDLs and the manufacturers may compromise the appropriateness of list formularies and may result in higher costs.⁴⁸ In addition, this process may remove practitioners from the development of these formularies.⁴⁹

Third, lists produced at the state level may not be as inclusive as a list that is created at a national level.⁵⁰ This is likely due to the differences in the formularies employed by each state's program.⁵¹ However, a national list would likely decrease costs and allow for bulk purchasing and aggregate discounts.⁵²

IV. CHALLENGES TO IMPLEMENTING A NATIONAL ESSENTIAL MEDICINES LIST IN THE UNITED STATES

There is considerable opposition to a national list from several key stakeholders. First, physicians are generally opposed to a national list

46. *Id.* (newer, more expensive drugs will consume more of the limited healthcare budget at the state level than generic drugs. This suggests there may be a requirement for better systematic selection of medication).

47. Ellner, *supra* note 43, at 1398 (the conflict occurs when pharmaceutical companies control PBMs and the development of PDLs by including more expensive medications on the PDLs).

48. *Id.*; see also Andrew Ellner et al, *Essential Medicines in the United States*, BMJ PUBLISHING GROUP, 12 (April 25, 2003) (the private management has been largely ineffective at controlling costs where the US spends almost twice as much per capita as other OECD nations and 40% of the elderly population lacks prescription drug coverage).

49. Ellner, *supra* note 43, at 1398.

50. Jonathan D. Ketcham & Jeffrey K. Ngai, *How Similar Are States' Medicaid Preferred Drug Lists?* 14 AMER. J. OF MANAGED CARE, SP46, SP48 (2008) (there is a degree of variation among the states regarding overlap of PDLs. Only 20 drugs out of a 110-drug survey were found to overlap over ten states in the survey).

51. *Id.* at SP50 (some of the variations in prices and cost effectiveness may be due to the different prices paid by each program, with different arrangements between the states and the pharmaceutical manufacturers).

52. Ellner, *supra* note 43, at 1399 (a national program would have more leverage in price negotiation than the current fragmented negotiation at the state level).

because the existence and widespread use of such a list may impact their “clinical freedom.”⁵³ Specifically, physicians may be concerned that their patients would have limited access to newer medications not included on the national list.⁵⁴ In addition, physicians may be concerned that they will not be adequately represented in the discussion and formulation of the national list.⁵⁵

Second, pharmaceutical companies are also opposed to a national list. The primary concern is that a national list would limit the types of drugs that may be prescribed within certain programs.⁵⁶ Industry opposition is most likely rooted in the fear that newer, more expensive drugs will not be included because of their cost, which could impact innovation and further research.⁵⁷

Third, patient groups are generally opposed to implementing a national essential medicines list.⁵⁸ Criticism from patient groups is based on concern that the list will be too limited and exclude beneficiaries of the program from the newest and most efficient prescription drugs.⁵⁹ In addition, organizations devoted to a specific disease expressed concern that medicines specific to that disease would be excluded without adequate substitutes.⁶⁰

Despite the opposition from physicians, the pharmaceutical industry, and patient advocacy groups, what is apparent is that the U.S. spends more on prescription drugs than most other Organisation for Economic Co-

53. *Id.*

54. Ellner et al, *supra* note 48, at 27.

55. *Id.*

56. *Id.* at 26 (the pharmaceutical industry is not opposed to coverage of all products but opposes coverage of a specific list because it would most likely exclude higher margin drugs. The pharmaceutical industry has also argued that such a list would curtail innovation by limiting profit and, theoretically, funds available for research and development).

57. Ellner, *supra* note 43, at 1399.

58. Ellner et al, *supra* note 48, at 27-28.

59. *Id.* at 28.

60. *Id.*

Operation and Development (OECD) nations.⁶¹ Therefore, the essential medicines list should be a collaboration of all interested parties.

V. CONCLUSION: SOLUTIONS FOR THE UNITED STATES AND CHINESE
SYSTEMS

China's national essential medicines list provides a template for the U.S. to develop and integrate an essential medicines list for the purposes of cost containment and greater access to necessary medicine. The current U.S. system should be improved because it is expensive and costs continue to rise, is under-inclusive, and there are potential conflicts when private interests develop a list absent active involvement from physicians and patient groups.

The benefits are considerable. First, patients' access to essential prescription medication would increase. Concern that medicines not included on the list would be unavailable is unfounded because those medications would still be accessible.⁶² Second, due to a better allocation of resources and purchases taking place at the national level, prescription drug spending would decrease.

Developing a national list in the U.S. would first need to overcome considerable opposition from physicians, the pharmaceutical industry, and patient groups. However, including and considering these interests in the development of an essential medicines list could overcome these obstacles. Therefore, developing a national essential medicines list in the U.S. would not only provide considerable healthcare savings and increase access to care, it is completely feasible.

61. *Id.* at 12.

62. The national list would not prohibit the use of other drugs. Rather, it would seek to better allocate limited resources by providing more coverage and reimbursement for drugs on the list.