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Christopher Sean Jackson

Incentives and Innovation: Pharmaceutical Research and Low-Income Groups Under the Proposed Medicare Prescription Drug Benefit

Christopher Sean Jackson[1]

Competing visions of a Medicare prescription drug benefit often differ dramatically in their treatment of low-income groups.[2] The profound implications of this treatment spread far beyond access to medical care, even reaching the process of technological innovation through which new drugs are produced. Low-income subsidies[3] under proposed versions of the Medicare prescription drug benefit will significantly alter the incentives pharmaceutical manufacturers face, possibly resulting in the unexpected emergence of more innovative drugs from the R&D process as research focuses on the special needs of low-income groups.[4]

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[1] J.D. Candidate, University of North Carolina School of Law, 2005. The author would like to thank Professors Scott Baker and Gail Agrawal for their valuable advice and comments.

[2] *See* Prescription Drug and Medicare Improvement Act of 2003, S. 1, 108th Cong. (2003), *available at* http://thomas.loc.gov; Medicare Prescription Drug and Modernization Act of 2003, H.R. 1, 108th Cong. (2003); *see also Strengthening Medicare: A Framework to Modernize and Improve Medicare*, *at* http://www.whitehouse.gov/infocus/medicare (last visited Nov. 9, 2003) (outlining the White House's version of a prescription drug plan) (on file with the North Carolina Journal of Law and Technology).

[3] Both S. 1 and H.R. 1 offer subsidies at various levels above the poverty line. Additionally, the inclusion of beneficiaries enrolled in both Medicaid and Medicare within the prescription drug benefit, referred to as "dual-enrollees," or "dual-eligibles" will be considered a "subsidy." Enrollees in Medicare who do not qualify for Medicaid, but who have incomes below seventy-four percent of poverty (the typical cut-off for Medicaid eligibility), will be referred to as "near-poor."

[4] For descriptions of both the innovative process and the regulatory apparatus that attends it, *see generally* DONNA E. SHALALA, ET AL., FROM TEST TUBE TO PATIENT: IMPROVING HEALTH THROUGH HUMAN DRUGS, U.S. Food and Drug Administration, *at* http://www.fda.gov/cder/about/whatwedo/testtube-full.pdf (Marcia L. Trenter ed., 1999) (providing general overview of FDA regulatory process) (on file with the North Carolina Journal of Law & Technology); *see also* MICHIE HUNT, THE NATIONAL INSTITUTE FOR HEALTH CARE

The different prescription drug benefit proposals highlight the impact of law and policy in shaping the course of science, healthcare, and the socioeconomic status of Americans. Among the many economic consequences of such a benefit, significant changes will occur in the technological innovation of new drugs as manufacturers respond and adapt to a different marketplace.[5] Evidence suggests that two primary forces will drive research toward more innovative outcomes. First, better access to drugs for low-income Medicare beneficiaries will increase drug demand and ease financial pressure on pharmaceutical producers to boost profits via minor variations of existing product lines.[6] Second, for a variety of reasons, aging low-income groups tend to be in poorer health than their higher-income peers, resulting in greater demand for technologically complex drugs.[7]

The Medicare prescription drug plan is a massive piece of legislation containing many controversial and complex provisions. This Recent Development will describe the impact of the treatment of low-income beneficiaries, including both "dual-eligibles"[8] and

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MANAGEMENT RESEARCH AND EDUCATIONAL FOUNDATION, CHANGING PATTERNS OF PHARMACEUTICAL INNOVATION (Nancy Chockley ed., 2002) (describing the FDA prioritization system and the various "levels" of innovation).

[5] Stimulating market demand is a well-known effect of government expenditure programs. *See* WILLIAM A. MCEACHERN, ECONOMICS: A CONTEMPORARY INTRODUCTION, ANNOTATED INSTRUCTOR'S EDITION 103–04 (4th ed. 1997); *see also* ROBERT L. HEILBRONER, TEACHINGS FROM THE WORLDLY PHILOSOPHY 276–79, 292–93 (1996) (outlining economist J.M. Keynes' views on society's propensity to consume and the ability of the government to stimulate this).

[6] *See* HUNT, *supra* note 4, at 15–16.

[7] This tendency is generally accounted for by reference to limited medical care in other areas. Higher income groups tend to have a higher level of preventive health maintenance, better access to medical information, etc. The availability of financial resources is a strong predictor of overall health. *See* JO C. PHELAN & BRUCE G. LINK, RESEARCH IN PROFILE, WHEN INCOME AFFECTS OUTCOME: SOCIOECONOMIC STATUS AND HEALTH, 2 (Robert Wood Johnson Found. Investigation Awards in Health Policy Research, Research in Profile, Issue 6, 2003), *at* http://www.ihhcpar.rutgers.edu/rwjf/downloads/research_in_profiles_iss06_feb2003.pdf (on file with the North Carolina Journal of Law & Technology).

[8] Dual-eligibles or "dual-enrollees" are beneficiaries who qualify for both Medicare and Medicaid benefits.

the "near-poor,"[9] on pharmaceutical innovation in the House and Senate proposals. If manufacturers shift the focus of their research toward more innovative technology, the resulting benefits to society will play an important role in offsetting the costs of such coverage.

In June of 2003, both Houses of Congress passed versions of a prescription drug coverage amendment to Medicare.[10] Americans overwhelmingly support a prescription drug benefit provision; a 2003 survey indicated that sixty percent believed that Congress should enact some sort of drug benefit.[11] Dramatic increases in drug-related spending over recent years have spurred political impetus for these plans.[12]

Not only is growth in prescription drug spending increasing, but the drugs are increasingly costly.[13] Pharmaceutical spending growth jumped from 1.1% in 1980 to 8.2% in 1990, hitting an alarming 17% by 1999.[14] Additionally, the Bureau of Labor Statistics calculated an average 4.9% increase in the

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[9] The near-poor are individuals with incomes below 200% of poverty, but who do not meet the minimum income and asset requirements to qualify for Medicare benefits.

[10] *See generally* S. 1; H.R. 1.

[11] THE KAISER FAMILY FOUNDATION/HARVARD SCHOOL OF PUBLIC HEALTH, MEDICARE PRESCRIPTION DRUG SURVEY, Chart 1, *at* http://www.kff.org/content /2003/20030903a/3374chartpack.pdf (Aug. 2003) (on file with the North Carolina Journal of Law & Technology).

[12] *See* Patricia M. Danzon & Mark V. Pauly, *Health Insurance the Growth in Pharmaceutical Expenditures*, 45 J.L. & ECON. 587 (2002). For a general overview of prescription drug spending trends in recent years, *see also* KAISER FAMILY FOUNDATION/HARVARD SCHOOL OF PUBLIC HEALTH, MEDICARE AND PRESCRIPTION DRUG SPENDING CHARTPACK, figs.9–10, *at* http://www.kff.org /content/2003/6087/6087v4.pdf (June 2003) (on file with the North Carolina Journal of Law & Technology) (analyzing projected increase in Medicare beneficiary expenditures) [hereinafter CHARTPACK]; *see also* KAISER FAMILY FOUNDATION, PRESCRIPTION DRUG TRENDS: A CHARTBOOK UPDATE, 18, *at* http://www.kff.org/content/2001/3112/RxChartbook.pdf (Nov. 2001) (tracking increases in pharmaceutical expenditures relative to other health care services) (on file with the North Carolina Journal of Law & Technology).

[13] Danzon & Pauly, *supra* note 12, at 587–88.

[14] *Id.* The improved efficacy of many drugs may be one explanation for this increase in consumption, as is the increasing breadth of prescription drug insurance coverage.

producer price index ("PPI") for the pharmaceutical industry from 1987–2002, compared with an average 1.95% increase in the PPI across all manufacturing industries.[15] In the absence of a drug benefit, average out-of-pocket expenditures for Medicare beneficiaries are projected to rise from $999 in 2003 to $1,454 in 2006.[16]

I. The Proposed Medicare Prescription Drug Benefit

In 2003, Congress attempted to address the increasing medical expenses of America's seniors by establishing a prescription drug benefit plan. Each house offered a different plan, and they currently are in committee debate as lawmakers attempt to reconcile key differences in the bills, such as the treatment of dually-enrolled beneficiaries.[17] Legislators, however, are having great difficulty reaching agreement and a vote on the final version of the bill is difficult to forecast.[18]

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[15] Bureau of Labor Statistics, *Producer Price Indexes*, *at* http://data.bls.gov/cgi-bin/surveymost?pc (last visited Nov. 9, 2003). Accounting for some (but not all) of the rapid growth in pharmaceutical PPI was a sudden spike in prices for psychotherapeutics, a small but significant class analyzed by the BLS when calculating PPI. For a more detailed evaluation of the impact of psychotherapeutics across the pharmaceutical industry, *see* Bureau of Labor Statistics, *Special Notice for Prescription Drugs Index*, *at* http://www.bls.gov /ppi/ppidrug.htm (last visited Nov. 9, 2003) (on file with the North Carolina Journal of Law & Technology).

[16] CHARTPACK, *supra* note 12, at fig.10.

[17] *See* KaiserNetwork.org, *Daily Health Policy Report: Group of Medicare Negotiators Reportedly Reach Compromise on Allowing Medicare Drug Coverage for Dual-Eligibles* (Oct. 2, 2003), *at* http://kaisernetwork.org /daily_reports/rep_index.cfm?DR_ID=20155 (on file with the North Carolina Journal of Law & Technology).

[18] *See* Julie Rovner & Emily Heil, *TANF Reauthorized, Gregg Pessimistic On Medicare Odds*, CONGRESS DAILY, Oct. 1, 2003. Although Congress is attempting to reconcile the significant differences in the two plans, compromise appears unlikely in the short term. If a vote is forced before certain key differences are worked out, it is probable that the benefit will be blocked altogether. Other significant stumbling blocks for the benefit include means-testing, and a provision that would allow Medicare to compete with private supplemental insurance programs. For a description of the debate, and possible compromises that may emerge, *see* Steve Turnham, *Barring changes, Dems*

At present, Medicare consists of Part A, which covers inpatient and critical access hospital costs, as well as short-term or rehabilitative nursing home costs, and Part B, which covers doctors' services and outpatient hospital costs.[19] Beneficiaries enroll separately in the two parts, and there is no premium for Part A enrollees who paid Medicare taxes during their working years.[20] Beneficiaries pay $840 for hospital stays up to 60 days, $210 per day for 60–90 days stays, $420 per day for 91–150 days, and all costs for hospital stays above 150 days.[21] The monthly Part B premium is $58.70 per month.[22] Enrollees pay a $100 deductible per calendar year for medical services plus 20% of after-deductible expenses.[23]

With limited exceptions, the Medicare plan does not cover prescription drugs.[24] Qualified beneficiaries may enroll in a Medicare + Choice plan at an extra cost and receive coverage for portions of prescription drug costs.[25] Additionally, certain Medigap plans offer some prescription drug benefits.[26] These plans typically are too expensive for low-income groups.[27]

'unable to support' prescription drug bill, at http://www.cnn.com/2003/ALLPOLITICS/10/23/congress.medicare/index.html (Oct. 23, 2003) (on file with the North Carolina Journal of Law & Technology).

[19] *Id.* at 11.

[20] *Id.* at 12.

[21] *Id.* at 31.

[22] *Id.* at 11.

[23] *Id.* at 12.

[24] *Id.* at 23. Some outpatient drugs are covered, such as certain oral cancer medications.

[25] For an overview of Medicare + Choice plans, *see id.* at 43–47.

[26] *See id.* at 43. For a general description of Medigap plans, *see* CENTER FOR MEDICARE AND MEDICAID SERVICES, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, MEDIGAP POLICIES: THE BASICS, *at* http://www.medicare.gov/Publications/Pubs/pdf/medigap_basics.pdf (2001) (on file with the North Carolina Journal of Law & Technology).

[27] *See* THE KAISER COMMISSION ON MEDICAID AND THE UNINSURED, THE PROPOSED MEDICARE PRESCRIPTION DRUG BENEFIT: A DETAILED REVIEW OF IMPLICATIONS FOR DUAL-ELIGIBLES AND OTHER LOW-INCOME MEDICARE BENEFICIARIES, 14, *at* http://www.kff.org/content/2003/4135/4135.pdf (Sept. 2003) (on file with the North Carolina Journal of Law & Technology) [hereinafter *Review for Dual-Eligibles*].

Medicaid offers a limited prescription drug benefit,[28] but Medicare beneficiaries with incomes or assets above approximately 74% of poverty do not qualify for Medicaid plans, and additionally may be unable to afford supplemental Medicare insurance.[29] These low-income individuals typically fall into one of several categories referred to as near-poor[30] and receive varying levels of subsidization under the prescription drug proposals. More than half of Medicare beneficiaries fell below the 200% line of poverty in 2001, amounting to more than 19 million beneficiaries.[31] Only 5.8 million of these qualified for prescription drug coverage under Medicaid as dual-eligibles.[32]

The House and Senate plans share a number of common features, including voluntary enrollment, a universal drug benefit with significant support for low-income beneficiaries, monthly premiums of approximately $35, overall costs of approximately $400 billion over 10 years, and the creation of a new agency within the Department of Health and Human Services to administer the drug benefit.[33] There are, however, significant differences. The Senate bill, S. 1, features a $35 per month premium with a $275 deductible and 50% coinsurance[34] between $275 and $4,500. Meanwhile, the House bill, H.R. 1, includes a $35 monthly premium and a $250 deductible, with a 20% coinsurance rate between $250 and $2,000. Above S. 1's initial coverage limit of

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[28] For an overview of the Medicaid benefit structure, *see* CENTER FOR MEDICARE AND MEDICAID SERVICES, MEDICARE: A BRIEF SUMMARY, *at* http://cms.hhs.gov/publications/overview-medicare-medicaid/default4.asp (last modified Sept. 25, 2003).

[29] *See Review for Dual-Eligibles*, *supra* note 27, at 14–15.

[30] *See, e.g.*, *id.* at 15.

[31] *See id.* at 14.

[32] *Id.* at 4.

[33] THE KAISER FAMILY FOUNDATION, THE CURRENT MEDICARE PRESCRIPTION DRUG DEBATE: BRIEFING CHARTS, figs.5–6, *at* http://www.kff.org/content /2003/6096/6096.pdf (2003) [hereinafter CURRENT MEDICARE DEBATE]; *see also* Prescription Drug and Medicare Improvement Act of 2003, S. 1, 108th Cong. (2003); Medicare Prescription Drug and Modernization Act of 2003, H.R. 1, 108th Cong. (2003).

[34] Coinsurance is a pay-per-use method of cost sharing, wherein the patient pays a percentage of costs per prescription filled.

$4,500,[35] beneficiaries must pay out-of-pocket until expenses reach the stop-loss threshold of $5,812.50. Then, Medicare resumes coverage with a 10% coinsurance rate.[36] This gap in coverage is known as the "hole in the doughnut."[37] H.R. 1 differs dramatically on this point, with an initial coverage limit of $2,000[38] and a stop-loss threshold of $4,900, a significantly larger hole in the doughnut.[39] Dual-enrollees in Medicaid retain their Medicaid coverage under S.1, and are not eligible for a Medicare drug benefit.[40] Under H.R. 1, dual-enrollees may enroll in the drug benefit, with Medicaid serving as a wraparound.[41] The differing treatment of low-income individuals is of particular significance. S. 1 allows beneficiaries to qualify for "low-income" coverage at higher levels of income than H.R. 1, due to its exclusion of dual-enrollees. Thus, according to Congressional Budget Office ("CBO") estimates, the Senate plan would cover approximately 4.5 million fewer low-income beneficiaries.[42] However, S. 1 gives its low-income beneficiaries significantly greater depth of coverage given the significantly higher initial coverage limit.[43]

Since beneficiaries must live well below the poverty line in order to qualify for Medicaid coverage, dual-enrollees are significantly poorer than other Medicare beneficiaries. More than 70% of dual-enrollees have annual incomes below $10,000,

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[35] S. 1, § 1860D-6(c)(3).

[36] CURRENT MEDICARE DEBATE, *supra* note 33, at figs.5–6.

[37] *See* HEALTH POLICY ALTERNATIVES, INC., THE HENRY J. KAISER FAMILY FOUNDATION, PRESCRIPTION DRUG COVERAGE FOR MEDICARE BENEFICIARIES: A SIDE-BY-SIDE COMPARISON OF S.1. AND H.R.1, *at* http://www.kff.org /content/2003/6103/6103.pdf (July 2003) (on file with the North Carolina Journal of Law & Technology).

[38] H.R. 1, § 1860D-2(b)(3).

[39] *See, e.g.*, *Review for Dual-Eligibles*, *supra* note 27, at 19.

[40] *See id.*, at 19–20.

[41] *Id.* at 8.

[42] THE KAISER FAMILY FOUNDATION, ISSUE PAPER: A PRESCRIPTION DRUG BENEFIT IN MEDICARE: IMPLICATIONS FOR MEDICAID AND LOW-INCOME MEDICARE BENEFICIARIES, *at* http://www.kff.org/content/2003/4136/4136.pdf, at 4 (2003) (on file with the North Carolina Journal of Law & Technology) [hereinafter ISSUE PAPER].

[43] *See Review for Dual-Eligibles*, *supra* note 27, at 19–20.

compared to 13% of all other Medicare beneficiaries.[44] Those near-poor beneficiaries who do not qualify for Medicaid assistance are likely to either avoid the costs of more expensive medication or skip doses in order to prolong their supply of already-purchased prescriptions.[45]

II. The Process of Pharmaceutical Innovation

The process of pharmaceutical innovation is both risky and costly, but with a potentially huge payoff both for the research firms and the society that stands to benefit from them.[46] For example, in 2002, Pharmaceuticals Research and Manufacturers of American ("PhRMA") estimated its domestic drug sales (for both prescription and over-the-counter drugs) at $145,213,400.[47] The U.S. pharmaceutical industry has increased its R&D expenditures as a percentage of domestic sales from 12% in 1970 to 18.2% in 2002.[48] Pharmaceutical manufacturers are highly sensitive to the projected demand for their products, given the high capital outlay required for drug research and the inherently risky nature of the process.[49] As a result of this high outlay, drug manufacturers do not charge the marginal cost of drug production, but instead allocate their total R&D costs by increasing the price of each pill that actually reaches the market.[50] The support a Medicare plan offers to low-income beneficiaries will dramatically shift demand for drugs consumed in large quantities by this population.[51] Accordingly, pharmaceutical research will direct itself toward this

[44] ISSUE PAPER, *supra* note 42, at 2.
[45] *Review for Dual-Eligibles*, *supra* note 27, at 15.
[46] *See, e.g.*, Stephen R. Latham, *Pharmaceutical Costs: An Overview and Analysis of Legal and Policy Responses by the States*, 24 J. LEGAL MED. 141, 147–48 (2003).
[47] PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA ("PHRMA"), PHARMACEUTICAL INDUSTRY PROFILE 2003, 79, *at* http://www.phrma.org/publications/publications/profile02/index.cfm (2003) (on file with the North Carolina Journal of Law & Technology).
[48] *Id.* at 79.
[49] *See* Latham, *supra* note 46, at 147–148.
[50] *Id.*
[51] Danzon & Pauly, *supra* note 12, at 602; *see also* HEILBRONER, *supra* note 5, at 276 (describing the impact of government expenditures on consumption).

expanded market, possibly altering the level of innovation seen in new drugs, as manufacturers focus their research toward the needs of low-income consumers.[52]

The FDA classifies new drug applications ("NDAs") in two ways: chemical type and therapeutic potential.[53] Drugs that offer substantial advances over existing compounds are given a priority classification, while those offering no significant improvement are given a standard classification.[54] NDAs with active ingredients that have never been approved by the FDA are termed new molecular entities ("NMEs"), those that feature an already-approved active ingredient or a slightly modified close chemical derivative are termed incrementally modified drugs ("IMDs"), and drugs with an identical approved active ingredient are "other drugs."[55] The FDA seeks to process priority applications within six months, whereas standard applications have a 10–12 month completion goal.[56]

The relative levels of drug innovation can be inferred by this system of prioritization. The "most innovative" drugs are priority NMEs, which feature new, previously-unapproved active ingredients and significantly increased therapeutic potential over existing medications.[57] Drugs then proceed from most to least innovative accordingly: standard NMEs, priority IMDs, standard IMDs, and other drugs.[58] During 1989–2000, fifteen percent of new drugs introduced were rated as priority NMEs, twenty percent were standard NMEs, eight percent were priority IMDs, forty-six percent were standard IMDs, and eleven percent were classified as "other drugs."[59] These figures show that only thirty-five percent of new drugs introduced during this time featured previously

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[52] *See* HUNT, *supra* note 4, at 15–17.
[53] U.S. FOOD AND DRUG ADMINISTRATION, *supra* note 4, at 35.
[54] *Id.* at 35.
[55] HUNT, *supra* note 4, at 4.
[56] CENTER FOR DRUG EVALUATION AND RESEARCH, FDA'S DRUG REVIEW AND APPROVAL TIMES, *at* http://www.fda.gov/cder/reports/reviewtimes/default.htm (last updated July 30, 2001) (on file with the North Carolina Journal of Law & Technology).
[57] HUNT, *supra* note 4, at 7.
[58] *Id.*
[59] *Id.* at 9.

unapproved active ingredients. The remaining sixty-five percent represent incremental shifts in technology.[60]

The prevalence of incremental technology over this time period is the product of numerous influences. Pharmaceutical firms are under pressure to increase profits while limiting massive R&D outlays.[61] The introduction of generics and the loss of patent protection severely erodes the profitability of older "blockbuster" drugs, leading manufacturers to focus on extending intellectual property protection[62] and to reduce capital expenditures by introducing less "innovative" products featuring the same active ingredients as established brands, but offering more convenient use or reduced side effects.[63]

III. The Role of the Prescription Drug Benefit in Stimulating Innovation

A prescription drug benefit may expand the market for newer drugs by encouraging low-income patients to switch from older, cheaper drugs to new, more expensive drugs.[64] Additional factors, both beneficial and detrimental, will further increase low-income demand for drugs.[65] This expanded market will induce drug manufacturers to seek realization of profits from this sector, spurring innovation.

At present, near-poor Medicare beneficiaries are uniquely vulnerable to under-use of drugs.[66] This population is "simultaneously more likely to be sick, less likely to have private Medigap" or employer-provided prescription plans, "not poor enough to qualify for Medicaid" support, yet not wealthy enough

[60] *See, e.g.*, HUNT, *supra* note 4, at 15–16.
[61] *See, e.g.*, PHRMA, *supra* note 47, at 76.
[62] HUNT, *supra* note 4, at 15–16.
[63] *See id.*
[64] *See* Danzon & Pauly, *supra* note 12, at 602.
[65] As discussed below, these factors include moral hazard and publicly subsidized demand stimulation, leading to inflation of prices. *See infra* note 72 and accompanying text.
[66] *See Review for Dual-Eligibles*, *supra* note 28, at 15.

to purchase all the drugs they require.[67] Low-income subsidies would serve to mitigate this under-use, increasing consumption, perhaps dramatically. Medicare beneficiaries are projected to spend $134 billion in 2006;[68] more than half of current Medicare beneficiaries fall below 200% of the poverty line and would be assisted by low-income subsidies.[69] A study of pharmaceutical use and socioeconomic status in Winnipeg indicated that the lowest income quintile consumed significantly more prescriptions than did higher quintiles; additionally the proportion of users to residents was higher, as was intensity of use by type of drug and expenditure per resident.[70]

Several characteristics unique to the health care marketplace, including the prescription drug industry, distort the typical supply and demand relationship present in most markets. The provision of insurance insulates the consumer from the cost of his consumption, leading to above-optimal consumption[71] and over-utilization of healthcare. This phenomenon is known as "moral hazard."[72] Its causes and effects are well documented in the study of insurance and economics, and it represents the most significant distorting factor caused by the provision of insurance

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[67] *See* Alyce S. Adams, Stephen B. Soumerai, & Dennis Ross-Degnan, *The Case for a Medicare Drug Coverage Benefit: A Critical Review of the Empirical Evidence*, 22 ANN. REV. PUB. HEALTH. 49, 49 (2001).

[68] *See* CHARTPACK, *supra* note 12, at fig.13.

[69] *See Review for Dual-Eligibles*, *supra* note 27, at 14–15.

[70] *See* Colleen Metge et al., *The Population's Use of Pharmaceuticals*, 37(6) MED. CARE 42, 49 (Supp. 1999). This is notable, as Canada's prescription drug coverage is often cited as a possible model for an American plan. Although the provisions in S.1 and H.R. 1 currently are not as generous as the Canadian coverage for lower-income groups, the effect on low-income drug consumption may be similar.

[71] Prices are at their optimal level where marginal benefit equals marginal cost. Where prices exceed optimal levels, there is an increased social cost for consumption of a good. In essence, consumers are not faced with the full price of their actions, leading them to consume more than would occur in a perfect market scenario. *See* THE MIT DICTIONARY OF MODERN ECONOMICS 262 (4th ed. 1992).

[72] Moral hazard is defined as "the effect of certain types of insurance systems in causing a divergence between the private marginal cost of some action and the marginal social cost of that action thus resulting in an allocation of resources which is not optimal." *Id.* at 291.

generally, and by public insurance in particular.[73] Moral hazard is typically treated as a negative effect, as it generally results in inefficient pricing and consumption,[74] resulting in higher consumption than the normal interaction of supply and demand.[75] Moral hazard presents a problem for economists and policy makers alike, and its negative effects, particularly inflated prices and expenditures, are of the utmost importance when defining the parameters of a major public insurance plan such as Medicare.[76]

Imperfect information in the hands of consumers is an additional factor that distorts the medical industry.[77] Patients rarely make their own decisions concerning pharmaceuticals, relying instead on physicians to determine the best course of treatment. These and other factors have the effect of making "drug demand stronger and less price-elastic than it might otherwise be."[78]

Given the propensity of dual-eligible and "near-poor" beneficiaries to experience more severe illnesses and require more

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[73] *See* Michael Chernew, *General Equilibrium and Marketability in the Health Care Industry*, 73 J. HEALTH POL. POL'Y & L., 885, 888 (2001); *see also* Mark V. Pauly, *The Economics of Moral Hazard*, 58 AM. ECON. REV. 531, 535 (1968) (describing moral hazard); *see generally* Willard G. Manning et al., *Health Insurance and the Demand for Medical Care: Evidence from a Randomized Experiment,* 77 AM. ECON. REV. 251, 251 (1987) (analyzing health care decisions and the impact of insurance).

[74] *See* Chernew, *supra* note 73, at 888.

[75] *See* Danzon & Pauly, *supra* note 12, at 611. Danzon and Pauly conclude that between one-fourth and one-half of the total growth in pharmaceutical spending between 1987 and 1996 may be accounted for by a direct moral hazard effect. *Id.*

[76] *See* Sherry A. Glied, *Health Insurance and Market Failure since Arrow*, 26 J. HEALTH POL. POL'Y & L. 957, 960 (2001).

[77] F.M. Scherer, *Pricing, Profits, and Technological Progress in the Pharmaceutical Industry*, 7 J. ECON. PERSP. 97, 99 (1993).

[78] *Id.* The price elasticity of demand is defined as "the responsiveness of the quantity demanded of a good to its own price." MIT DICTIONARY, *supra* note 71, at 342 (A relatively elastic demand curve for a good indicates higher substitutability; consumers respond to price increases by reducing their consumption of the more expensive substitute.).

prescriptions to treat them,[79] an expansion of the low-income market could lessen the impetus toward incremental technological innovation in the pharmaceutical field.[80] Stimulating low-income demand will offer manufacturers additional incentives to focus on more innovative pharmaceutical technology in two important ways. First, the addition of this consumer base alone will provide a greater profit margin to drug companies, which will relax pressure to pad margins by pushing incremental improvements in already-approved drugs.[81] Second, the already-noted tendency of the lowest income groups to consume more prescriptions per beneficiary, resulting from a higher likelihood of severe illnesses,[82] and to require more complex (and often multi-systemic) medications,[83] provides manufacturers incentive to explore and develop new active ingredients. Expanded insurance coverage is "likely to make it worthwhile for companies to launch more new drugs per therapeutic class and to develop more formulations and indications per molecule."[84]

However, new drugs are also likely to be more expensive, increasing the strain on the Medicare budget.[85] Priority NMEs are two-and-a-half times more expensive than older drugs, with an average of $91.20 per prescription versus $37.20.[86] Potential cost

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[79] *See Review for Dual-Eligibles*, *supra* note 27, at 5; *see also* Metge et al., *supra* note 70 (indicating that lower-income quintiles have special drug requirements).

[80] *See* HUNT, *supra* note 4, at 15–16.

[81] *See id.* at 16 (indicating that ncreased demand from a previously untouched segment of the market (i.e., low income groups) may serve to lessen the financial pressures Hunt describes).

[82] *Review for Dual-Eligibles*, *supra* note 27, at 5; *see also* Phelan & Link, *supra* note 7, at 2 (describing relationship between lower incomes and increased incident of disease).

[83] *See Review for Dual-Eligibles*, *supra* note 27, at 5.

[84] Danzon & Pauly, *supra* note 12, at 602 (detailing the extremely complex relationship between insurance and the rate of pharmaceutical innovation and its impact on total drug expenditures, and offering the alternative hypothesis that the increase in pharmaceutical technology itself may lead to more demand for expanded coverage, which feeds back to increase demand for new drugs, increasing prices).

[85] *See* HUNT, *supra* note 4, at 14.

[86] *Id.*

reductions in other areas may offset this strain,[87] and the savings realized from avoiding more expensive and invasive medical care may be significant.[88] However, Congress should be aware of the tendency for new technological breakthroughs in medicine to lead to a demand for more insurance coverage.[89] This tendency, combined with an already fragile fiscal situation, could require taxpayers to make a greater financial commitment to Medicare than they are prepared to make.

Bearing in mind budgetary difficulties, the degree to which demand stimulation and increased innovation might be accomplished varies depending on the depth and width of the coverage offered to low-income groups. H.R. 1 covers significantly more low-income beneficiaries due to its inclusion of dual-enrollees.[90] However, this coverage is not as extensive as that in S. 1, given the much lower initial coverage limit of $2,000.[91] The hole in the doughnut is created by the gap between this low initial coverage limit and the stop-loss threshold of $3,500.[92] As a result of this hole, beneficiaries are uncovered for expenses incurred up to the stop-loss threshold.[93] Beneficiaries at this income-level are extremely price-sensitive,[94] and may significantly

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[87] *See* Scherer, *supra* note 77, at 113.

[88] *See* Frank R. Lichtenberg, *Are The Benefits of Newer Drugs Worth Their Cost? Evidence From The 1996 MEPS*, HEALTH AFF., Sept./Oct. 2001, at 250.

[89] *See* Danzon & Pauly, *supra* note 12, at 602.

[90] *Review for Dual-Eligibles*, *supra* note 27, at 6.

[91] Medicare Prescription Drug and Modernization Act of 2003, H.R. 1, 108th Cong. (2003), 1860D-2(b)(3).

[92] The stop-loss threshold is essentially a catastrophic level of out-of-pocket spending. H.R. 1 acts to mitigate catastrophic out-of-pocket expenses by resuming coverage at this level.

[93] *Review for Dual-Eligibles*, *supra* note 27, at 20.

[94] *See* Arthur A. Nelson, C. E. Reeder, & W.M. Dickson, *The effect of a Medicaid drug copayment program on the utilization and cost of prescription services*, 22(8) MED CARE 724, 724 (1984); C. E. Reeder & Arthur A. Nelson, *The differential impact of copayment on drug use in a Medicaid Population*, 22 INQUIRY 396 (1985). Nelson et al. found that following the implementation of a 50¢ copayment per prescription in South Carolina's Medicaid program, claims dropped from 24.8 to 23 claims per prescription per recipient per year. The subsequent study determined that the copayment caused a significant change in use of cardiovascular, cholinergic, diuretic, and psychotherapeutic drugs. See Adams, Soumenai, & Ross-Degnan, *supra* note 67, at 54 for a discussion of

reduce drug consumption after the initial coverage limit, never reaching the stop-loss threshold.[95]

The sizable hole in the doughnut would lessen the enhanced demand effect of the benefit under the House bill, not only due to the size of the hole in the doughnut, but also because the relatively low initial coverage limit.[96] If beneficiaries begin to reduce their drug consumption at this point (likely never reaching the stop-loss threshold in most cases), a sizable portion of the prescription drug requirements of the sickest and poorest enrollees could go unaddressed; low-income demand for technologically innovative drugs would decrease accordingly.

The introduction of NMEs is valuable to both the healthcare system and to the economy. A recent study of medical expenditure data indicates that new drugs are of better quality than older drugs and that the introduction of new drugs reduces morbidity and mortality, as well as spending on a variety of other non-drug medical services.[97] New drugs also lead to fewer missed work days.[98] The emerging use of genomics in the pharmaceutical field may further enhance the value of new drugs if R&D costs decrease[99] and if medicine becomes increasingly cost-effective.[100] Overall, it would appear that new technology is beneficial, both from an economic and a medical perspective.

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other controlled studies concerning the impact of copayments on the use of prescription drugs.

[95] *Review for Dual-Eligibles*, *supra* note 27, at 15.

[96] H.R. 1, § 1860D-2(b)(3).

[97] *See* Lichtenberg, *supra* note 88, at 250. Lichtenberg relies on the "quality ladder" model of innovation, which favors new innovations to older products due to a higher ratio of services offered in relation to their cost of production.

[98] *Id.* at 250.

[99] *See* Arti K. Rai, *The Information Revolution Reaches Pharmaceuticals: Balancing Innovation Incentives, Cost, and Access in the Post-Genomics Era*, 2001 U. ILL. L. REV. 173, 180 (2001) (arguing that the use of genomics will offer some reduction in research and development costs).

[100] *Id.* at 205.

IV. Balancing Costs and Benefits

From the perspective of public finance, support for dual-eligibles and the near-poor under a Medicare prescription drug benefit program effectively represents a subsidy to drug manufacturers. Although many criticize the already-high profits of drug companies, society benefits from encouraging and fostering research in new and more innovative pharmaceutical technology.[101] It may be fairly said that

> assuming that important new drugs yield substantial consumer surplus [otherwise] untapped by their developers, consumers . . . lose along with the drug companies. Should a tradeoff be required between modestly excessive prices and profits versus retarded technical progress, it would be better to err on the side of excessive profits.[102]

The importance of innovative pharmaceuticals to society, as well as the laudable goal of the provision of enhanced medical care to low-income groups, should be weighed carefully against the need for fiscal deliberation.[103] There is evidence that just as insurance shifts demand for drugs, so newer, better drugs shift demand for insurance.[104] Already, Medicare is in near-constant danger of fiscal insolvency; legislators must anticipate the rising costs of healthcare generally, as well as the emergence of more expensive pharmaceuticals, when crafting the prescription drug benefit.[105]

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[101] Scherer, *supra* note 77, at 102.

[102] *Id.* at 113.

[103] *See* HUNT, *supra* note 4, at 18; *see also* Rai, *supra* note 79, at 179 (describing pricing distortions as a result of insurance).

[104] *See* Danzon & Pauly, *supra* note 12, at 602.

[105] *See, e.g.*, *The Health Insurance Crisis*, N.Y. TIMES, Oct. 2, 2003, at A30 (discussing a variety of problems relating to health insurance, including federal Medicare budgets, state Medicaid efforts and budget crises, and employer-related concerns).

Additionally, other provisions within the Medicare prescription drug benefit plan, such as price control schemes[106] and a stricter use of formularies,[107] could greatly reduce any positive effect on pharmaceutical innovation. These would provide a significant disincentive to innovate, given the already-noted financial pressures on manufacturers to satisfy investors with sizable profits.[108] Society must consider whether it is willing to risk high prices in one arena in exchange for high returns in another.[109]

Often it is easy to mischaracterize the relationship between insurance and drug prices and the impact on society of increased prices.[110] Although the contribution of moral hazard to more expensive pharmaceuticals is marked, "there is no obvious basis for labeling the insurance-induced rise in drug expenditures as inefficient relative to other health care spending."[111] Indeed, if an ethical examination of the tendency for low-income groups to under-utilize drugs is made, such stimulation of consumption may be nothing other than positive, within certain limits.[112]

The benefits conferred upon society—reduced mortality, mitigated illness, decreased missed workdays, increased economic gain, and advanced medical technology—play a large role in the calculus of costs and benefits surrounding Medicare questions.

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[106] *See* Scherer, *supra* note 77, at 106. Both proposed plans feature extensive "best price" negotiation elements. *See* HEALTH POLICY ALTERNATIVES, INC., *supra* note 37, at 7.

[107] *See* HEALTH POLICY ALTERNATIVES, INC., *supra* note 37, at 6 (describing formularies and covered drugs). Each bill proposes a similar use of formulary lists, but it remains unclear how strictly they may be employed. *Id.*

[108] *See* HUNT, *supra* note 4, at 15–16.

[109] Scherer, *supra* note 77, at 113.

[110] For example, Lichtenberg finds in an empirical analysis with three dependent variables (mortality, morbidity, spending for non-drug medical events) that a price increase of $18 per prescription for "new drugs" is offset by a $71.09 reduction in non-drug spending. *See* Lichtenberg, *supra* note 88, at 248.

[111] Danzon & Pauly, *supra* note 12, at 612; *see also* Scherer, *supra* note 77, at 103–04 (downplaying debate over pharmaceutical industry returns).

[112] Phelan and Link theorize that the gap between wealth/health and poverty/disease may actually be increasing, as access to new technology and information is limited for low-income groups. *See* Phelan & Link, *supra* note 7, at 3.

These benefits have the potential to spill over from the low-income population addressed by the Medicare prescription drug benefit to a host of other demographics, crossing boundaries of age, working status, and income level. Non-prescription medications may similarly undergo more significant innovation as newly-developed technology finds its way into other drugs. Taken with a measure of fiscal caution and foresight, generous treatment of low-income beneficiaries under a Medicare prescription drug benefit may have a lasting positive impact for society at large, from economic, medical, and technological perspectives.

V. Author's Postscript

After the completion of this Recent Development and during the final editing process, Congress adopted a conference agreement reconciling the House and Senate bills.[113] President Bush signed the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 into law on December 8, 2003.[114] The provisions in the adopted bill are largely a compromise between those in the House and Senate versions.[115] The treatment of low-income groups in the final bill generally reflects those recommendations made in this Recent Development: dual-eligibles are included in the benefit;[116] the hole in the doughnut is

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[113] H.R. REP. NO. 108-391 (2003), *available at* http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=108_cong_reports&docid=f:hr391.108.pdf (on file with the North Carolina Journal of Law & Technology).

[114] Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173 (Dec. 8, 2003) (to be codified in scattered sections of 42 U.S.C.). *See* CNN, *Bush Signs Landmark Medicare Bill into Law, at* http://www.cnn.com/2003/ALLPOLITICS/12/08/elec04.medicare/index.html (Dec. 8, 2003) (on file with the North Carolina Journal of Law & Technology).

[115] For a summary comparison of the three bills, *see* HEALTH POLICY ALTERNATIVES, INC., THE HENRY J. KAISER FAMILY FOUNDATION, PRESCRIPTION DRUG COVERAGE FOR MEDICARE BENEFICIARIES: A SIDE-BY-SIDE COMPARISON OF S.1 AND H.R. 1, AND THE CONFERENCE AGREEMENT (H.R. 1), *at* http://www.kff.org/medicare/loader.cfm?url=/commonspot/security/getfile.cfm&PageID=28003 (Nov. 2003) (on file with the North Carolina Journal of Law & Technology).

[116] Medicare Prescription Drug, Improvement, and Modernization Act of 2003 § 1935(c)(6).

significantly smaller with an initial coverage limit of $2,250,[117] and catastrophic coverage resumes at $3,600.[118] These provisions represent a more generous treatment of low-income groups than those in earlier bills and should result in the development of more technologically innovative drugs once the pharmaceutical industry feels the impact of the benefit.

[117] *Id.* at § 1860D-2(b)(3).
[118] *Id.* at § 1860D-2(b)(4)(B).