The 340B benefit program

Why we should care about both its intentions and outcomes

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In 1982 a well-intentioned federal agency was created to improve health care for those who are geographically isolated and economically or medically vulnerable. One of its programs, termed 340B, established in 1992, mandated that pharmaceutical manufacturers provide outpatient drugs at major discounts to certain healthcare entities including hospitals (eligible “covered entities”). Savings thus generated could in turn serve a hospital’s charitable non-profit services to low income uninsured patients. The 340B statute clearly delineated what eligible entities are but did not specify or obligate the entities as to *how* program savings should be used or shared. Do these savings translate to better health care? We find that the data reveal mixed results in this regard.

This law, while successful at many of its missions, has come under scrutiny by the Office of Inspector General (OIG) and the Congress.^{1,2} The 340B Program is complex, not transparent and complicated. Its original intended aims and the current operational reality diverge. It is multi-layered with opaque discount costs. At times savings from discounted prices are not used with charitable care as its primary target. Many neurologists may be unaware of this program; but its benefits and shortcomings can affect our practices.

In this issue of the *Neurology® Clinical Practice*, Whittington et al.³ painstakingly illustrate one undesirable aspect of 340B program that will surprise many of us. The authors calculate cost-effectiveness using variable hypothetical pricing structures for fingolimod. The prices used for calculating value and quality-adjusted life-years (QALY) vary depending on whose pricing data are used. Thus, because of this variability, a drug’s cost-effectiveness could easily fall below or above commonly accepted thresholds. Eligible entities purchase drugs at deep discounts, but receive payer reimbursements at much higher rates. The e-table in Albrecht’s reference⁴ gives a peek at how discounted 340B prices differ from non-340B rates for some neurology drugs. So, what then are the surprises awaiting us?

First is the determination of cost-effectiveness. A drug takes a tortuous 5–7 step variable pricing route from manufacturers to providers and patients. Figures from Whittington et al.³ and others^{1,5} illustrate these steps; however, if sale prices vary widely, due to lack of transaction transparency, then cost-effectiveness estimates are unreliable. Payer coverage policies may thus depend on which pricing step they choose to follow. Any coverage policy favoring one drug over another, by using uncertain preferred cost estimates, could be biased. Mastering the circuitry of the basal ganglia is more rewarding and easier than deciphering 340B drugs’ *ex vivo* peregrinations.

A second surprise, outside the scope of Whittington’s article, will still need our attention. Entities (e.g., hospitals) are allowed to receive Medicare reimbursement rates regardless of whether they purchased drugs at discounted 340B or higher (non-340B) prices.^{4,6,7} Some authors have suggested that the discounted drugs are used for patients with “generous” insurance benefits.^{6,8,9} Higher insurer payments for discounted purchases has been identified as a profit source with unhealthy and uncharitable consequences. These could include hospital acquisition of physician practices,⁸ possibly even neurologists’. In response, the Centers for Medicare and Medicaid Services (CMS) elected to reduce 340B drug payment (Medicare

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Part-B) to hospitals commencing in 2018 at the urgings of the OIG and other advisory bodies. Instead of the current hospital reimbursement at average sales price (ASP) plus 6%, CMS will now reimburse at ASP minus 22.5%.² As a result, safety-net hospitals may have to curtail their services, and the trend towards hospitals acquiring physician practices could reverse. The CMS decision, not uniformly welcomed, is expected to be appealed.

The third surprise is the longevity and growth of this unfamiliar federal program. Its complexity and confidential pricing structures were partly responsible for the misdirected profits.^{2,6} The Department of Health and Human Services administers the 340B through its Health Resources and Services Administration (HRSA). It administers Medicare and Medicaid via the CMS. Interagency interactions, transparency levels, and oversight of these disparate agency programs and benefits vary. We, healthcare providers, feel the weight of Medicare's close scrutiny. This stands in contrast to the lightly placed requirements expected of the 340B program.

The authors deserve praise for drawing our attention to this abstruse program, one with oversized importance to a segment of patients and providers. Neurologists care intensely about our charitable missions but do not realize the effect of 340B in our daily practices.¹⁰ They would if a payer policy denies coverage on the basis of questionable cost estimates. Whittington et al.'s analysis offers us a timely opportunity to learn a bit more about this pharmacy benefit. It had laudable intentions but its latter-day consequences were unanticipated. In a much-debated 1975 interview, Milton Friedman observed, "One of the great mistakes is to judge policies and programs by their intentions rather than their results."

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S. Satya-Murti: drafting/revising manuscript.

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References

1. Gerlach J, McSweeney S, Swearingen A, Patil N, Coustasse A. Benefits of the 340B drug discount program. Poster presented at: The Lewis College of Business Research Day; November 10, 2017; Huntington, WV.
2. Department of Health and Human Services, Office of the Inspector General. Examining HRSA's oversight of the 340B Drug Pricing Program: testimony of Erin Bliss before the U.S. House of representatives. Available at: oig.hhs.gov/testimony/docs/2017/bliss072017.pdf. Accessed July 18, 2017.
3. Whittington M, Campbell J, McQueen R. Achieving high-value care for all and the perverse incentives of 340B price agreements. *Neur Clin Pract* 2018;8: 148-152.
4. Albrecht J, Mudahar S. The reach of the 340B drug pricing program. *JAMA Dermatol* 2015;151:923-924.
5. Fein AJ. Challenges for managed care from 340B contract pharmacies. *J Manag Care Spec Pharm* 2016;22:197-203.
6. Conti RM, Bach PB. The 340B drug discount program: hospitals generate profits by expanding to reach more affluent communities. *Health Aff Proj Hope* 2014;33: 1786-1792.
7. Kantarjian H, Chapman R. Value of the 340B drug discount program. *JAMA Oncol* 2015;1:1029-1030.
8. Desai S, McWilliams JM. Consequences of the 340B drug pricing program. *N Engl J Med* 2018;378:539-548.
9. Gellad WF, James AE. Discounted drugs for needy patients and hospitals—understanding the 340B debate. *N Engl J Med* 2018;378:501-503.
10. Berger JR. The financial contribution of the multiple sclerosis specialist. *Neurol Clin Pract* 2017;7:246-255.