Estimating a Drug's Price After Loss of Exclusivity As a Function of the Cost of Goods Sold

Melanie D. Whittington[1], PhD, MS & T. Joseph Mattingly[2], PharmD, MBA, PhD
[1]Valusphere, LLC, [2]Drugscope, Inc.

OBJECTIVE. Determine if a drug's cost of goods sold (COGS), which is a function of the marginal costs of production and the cost of shipping, predict its price after loss of exclusivity.

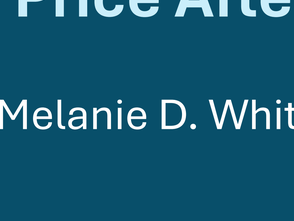
BACKGROUND. Nearly all published cost-effectiveness analyses omit future drug pricing dynamics despite recommendations from the Second Panel of Cost-Effectiveness in Health and Medicine and an ISPOR Task Force Report. Recent attempts to incorporate drug price dynamics within cost-effectiveness analyses have assumed a price reduction of 76% after loss of exclusivity. Assuming a 76% price reduction and applying this universally for all drugs ignores important drug-specific attributes that likely better predict the post-loss of exclusivity price.

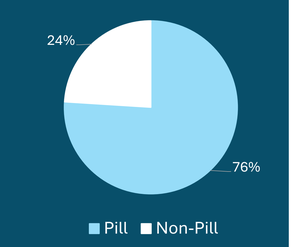
METHODS. Published literature and financial statements from 20 generic manufacturers were reviewed to identify the average manufacturer mark-up over COGS. Then stakeholder engagement with 3 small molecule generic and 2 biosimilar manufacturers was conducted to identify key drivers of generic/biosimilar prices and COGS. Cost data was abstracted from the Mark Cuban Cost Plus Drug Company (MCCPDC). Based on literature and stakeholder feedback, COGS were calculated as half of the manufacturer price as reported in the MCCPDC.

ECONOMIC THEORY FRAMING WORK. In an environment without market friction and where competitors can produce the same type of commodity, the equilibrium price will approach COGS.

SAMPLE

Form	Count	% of Total
Tablet/Capsule	1,620	75.6%
Topical	179	8.4%
General Liquid	145	6.8%
Specialty Liquid	70	3.4%
Patch	32	1.5%
Topical	26	1.2%
Suspension Packet	19	0.9%
Nasal Spray	15	0.7%
Combination Inhaler	8	0.4%
Foam Canister	6	0.3%
Gel Packet	5	0.2%
Granules	5	0.2%
Single Drug Inhaler	3	0.1%
Gum	2	<0.1%
Syringe	2	<0.1%
Auto-Injector Pen	1	<0.1%
Pads	1	<0.1%
Spray	1	<0.1%
Swabs	1	<0.1%
Vaginal Ring	1	<0.1%
TOTAL	2,142	**100%**

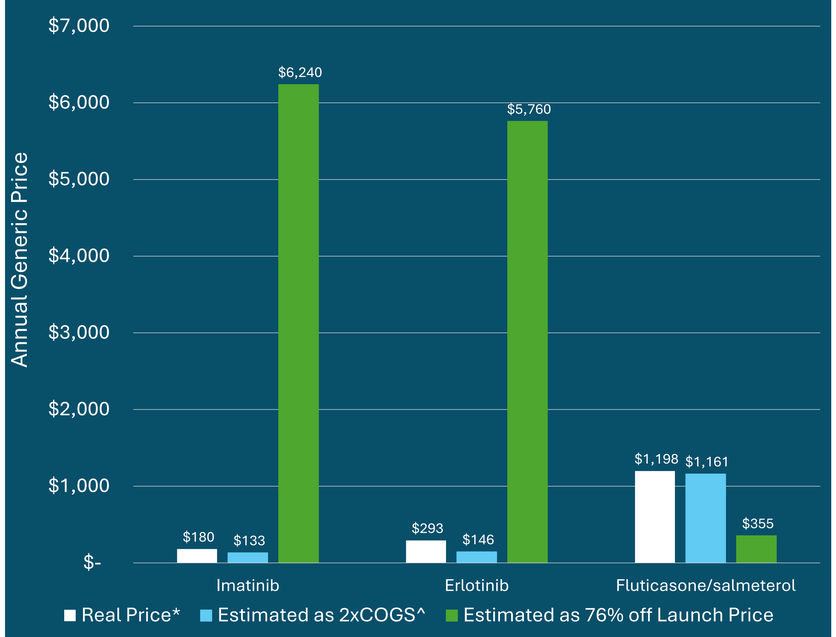




ESTIMATES OF COGS

Form	90th Percentile	75th Percentile	50th Percentile	25th Percentile	10th Percentile
Tablet/Capsule (per pill)	$1.82	$0.36	$0.09	$0.04	$0.02
Topical (per g)	$1.36	$0.50	$0.17	$0.07	$0.03
General Liquid (per mL)	$1.69	$0.59	$0.15	$0.04	$0.02
Specialty Liquid (per mL)	$5.26	$3.26	$0.93	$0.33	$0.14
Patch (per patch)	$3.37	$3.22	$2.33	$0.67	$0.37
Topical (per mL)	$1.21	$0.35	$0.16	$0.09	$0.05
Suspension Packet (per packet)	$7.48	$3.55	$2.33	$0.41	$0.22
Nasal Spray (per device)	$36.05	$24.40	$15.61	$8.41	$6.37
Combo Inhaler (per device)	$133.99	$104.51	$82.39	$41.88	$25.00
Foam Canister (per g)	$2.95	$1.87	$1.46	$0.79	$0.45
Gel Packet (per packet)	$1.28	$1.28	$1.28	$1.28	$1.28
Granules (per g)	$2.30	$0.17	$0.08	$0.04	$0.03
Single Drug Inhaler (per device)	$16.74	$14.86	$11.73	$8.54	$6.62
Gum (per piece)	$0.08	$0.08	$0.08	$0.08	$0.08
Syringe (per mL)	$9.50	$8.00	$5.50	$3.00	$1.50
Auto-Injector Pen (per kit)	$16.93	$16.93	$16.93	$16.93	$16.93
Pads (per pad)	$0.55	$0.55	$0.55	$0.55	$0.55
Spray (per g)	$11.77	$11.77	$11.77	$11.77	$11.77
Swabs (per swab)	$0.18	$0.18	$0.18	$0.18	$0.18
Vaginal Ring (per ring)	$16.33	$16.33	$16.33	$16.33	$16.33
AVERAGE	$2.71	$0.54	$0.12	$0.04	$0.02

COMPARISON OF ESTIMATION APPRAOCHES



*As reported in the MCCPDC data as the manufacturer price before mark-ups added by the MCCPDC.
^The form-specific, median COGS estimate generated from this analysis was used in this calculation.

IMPLICATIONS. Cost-effectiveness analyses should incorporate genericization to better represent the true opportunity costs. This study provides an evidence-based approach to estimate a drug's price after loss of exclusivity to be incorporated within these analyses. Assuming a uniform 76% price reduction for all drugs ignores important drug-specific attributes. This study empirically demonstrates that estimating the drug's price after loss of exclusivity as a function of two times its COGS more appropriately captures these drug-specific attributes.

Contact Information: Melanie D. Whittington, PhD, MS, mwhittington@valusphere.com and T. Joseph Mattingly, PharmD, MBA, PhD, joey.mattingly@drugscope.com
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