

Book Forum:

Jeremy Greene's *Generic: The Unbranding of Modern Medicine*

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Welcome to our inaugural “Book Forum.” Our aim is simple: to promote lively exchange between a group of scholars and an author, allowing for experimental and inventive engagements that are not so much about evaluation but rather draw on concepts and shared commitments. It’s probably worth noting that *Somatosphere* will continue to feature book reviews, which have been a mainstay from the beginning. Our hope is that the forums will follow along a well-trod path made by the reviews, into new clearings.

Our first book is [Jeremy Greene’s *Generic: The Unbranding of Modern Medicine*](#) (Johns Hopkins University Press, 2014). Greene’s book is a dizzying historical-political-social-cultural account of the forms generic drugs have taken over past several decades. The book is a story about the development and circulation of these drugs—their makers and consumers, advocates and detractors, within and between the domains of ethics and markets—as “generics” stir debate and catalyze change (seen and unseen, felt and unperceived) in the healthcare marketplace.

We hope you enjoy the forum. We have more planned in the coming months, which will include books by Warwick Anderson, Sameena Mulla, Lisa Stevenson, and Christian McMillen.



Generic virtue and vice

Anne Pollock

Georgia Institute of Technology



Generic drugs are fundamentally ambivalent, as expertly explored in Jeremy Greene's book *Generic: The Unbranding of Modern Medicine*. The ambivalences are articulated in different forms throughout the book, such as the hope for *rational prescribing* versus the fear of *rationing*, and the promise of spreading innovation through making pharmaceutical access affordable, versus the worry about impeding innovation through discouraging investment in R&D. For me, the most striking binary was another pleasingly alliterative pairing: that generic drugs can signify both *virtue* and *vice*.

In the first few pages, we read about a pair of scandals demonstrating extremes of the spectrum. First, in 1987 an FDA official serves jail time for accepting, and failing to report, a free lunch from businesspeople in the generic industry – an industry which is engaged in egregious fraudulent practices and which he is charged with regulating. This scandal is twinned with another: research showing generic similarity is suppressed by the branded company that funded it, and the virtuous scientist strives to expose the truth against the company that funded her work. These two stories are far more melodramatic than most of what comes later in the book, which is less about outright fraud and valiant science than about the shades of gray that are inherent in the creation and promotion of things that are “the same but not the same.”

To highlight the danger of generic vice, brand-name companies have sometimes blurred the distinction between generic and anonymous. Anonymity feels risky. Greene includes a fabulously paranoid 1967 pharma ad with a creepy image of business people on a sidewalk, their featureless faces and necks completely covered, with the headline “Drugs Anonymous?” I have

argued elsewhere that part of the appeal of brand-name drugs is the commodity fetishism that imputes more value to what is more expensive, but of course there is also a serious issue here of trust. In the terrain of consumer goods, pills are particularly opaque, and we rely on regulation and brands in order to trust. The generic industry has sought to cultivate trust, too, sometimes by showing its face. *Branded generics* emerged to overcome accusations of anonymity, and also take advantage of the association of expense with value with their promise of “cheap, but not risky cheap,” and “reassuringly expensive.”

Frustratingly for the brand-name companies that are the descendants of “ethical manufacturers,” generic drugs are often described in a way that has a sheen of moral superiority over brands. The generic industry is neither inherently moral nor immoral, but rather, as is typical of corporations broadly, it is *amoral*. The generic sector is a profit-seeking industry like any other. Public health advocates, especially those focused on global access to pharmaceuticals, often highlight the virtue of generic drugs, fostering the impression that companies provide drugs for the poor out of the goodness of their hearts rather than as a commercial venture. Greene both shows why that impression exists and punctures the mystique.

A final thought on vice, in relation to one more term sometimes applied to generics that struck me as evocative: *adulteration*. Of course there is a technical meaning here: replacing more expensive ingredients with less valuable or inert ones. But it has a resonance with *adultery*: cheating, stepping out, breaking our loyalty with the brands with whom we have a relationship in order to see if we can find something else to fill our needs and desires. Unfortunately for branded pharma, the logic of savvy consumerism makes it a virtue to be always on the lookout for better offers.

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Read this piece online at: <http://somatosphere.net/forumpost/generic-virtue-and-vice>

Nostalgia is always about the present

Nancy Campbell

Rensselaer Polytechnic Institute

Generics have indeed become economically, clinically, and culturally relevant objects and subjects. But they will never have the emotional and intangible force of the brand.

I grew up in a household chock full of pharmaceutical objects, the flotsam and jetsam of a grandfather and father joined in family practice, their offices practically in our back yards and managed by my grandmother and mother. From clocks to refrigerator magnets to soap to Q-tip dispensers to pens to stuffed animals to paper products of every conceivable size and shape, the form of the brand-name pill pervaded my youth. Ours was a family constituted around delivery of cradle-to-grave medical services, and so these pharmaceutical objects were as familiar to us as M&Ms or Tang. Brand loyalty was equated with quality you could trust. There were only a few bad words in my parents' household—one was “chiropractor,” one was “stupid,” and the other was “generic.”

Somehow, the politics of pharmaceutical manufacturers were integral not only to the practice of medicine but for political identity and subject formation, just as surely as if we were the children and grandchildren of Parke Davis, Merck, or Eli Lilly employees. No more does that tight-knit corporate subjectivity of the global North exercise the same powerful hold. Undone by downsizing and globalization, I buy my cut-rate prescription via Ranbaxy or one of the other generic Goliaths hailing



from the global South. Having shed the brand loyalties of my youth, no longer cued by the ephemeral domestic detritus of Big Pharma, I treasure my “It’s Time for Viagra” clock (though the minute hand is sadly broken) and the tiny Asendin teeter-totter bequeathed to me by my father to see me through the vicissitudes of adolescence that rests upon my office window sill reminding me to gently ride the vicissitudes of middle management. But somehow sildenafil and amoxapine just don’t have the same poetic ring to my ear as Viagra and Asendin.

My pharmaceutical-brand-name-free existence is punctuated when I tune into the tube. But I confess to a sense of nostalgia for the comfort brands as evocative for me of the 1970s and 1980s as the pre-Walmart smiley face. That says something about the “intangible qualities” to which pointed Henry DeBoest, an Eli Lilly VP testifying before Gaylord Nelson and quoted in Jeremy Greene’s blow-by-blow account of the kaleidoscope of rapidly reconfiguring “interests” that emerged in the course of these decades-long disputes. There was ample fear and loathing on all sides, whether anti-genericists or “rabid” or “frothing” consumerists.” There are “cults” and “crusaders,” but surprisingly few clear-cut demons or heroes in the land of the generics, which appears shadowed in many shades of grey. Sometimes specificity matters; sometimes it does not. In the end, it may not matter whether we think of the questions posed by generic “substitution” as unresolvable or not, because it seems that questionable resolutions will be our only answers in the unreasonable rationalities of marketized healthcare to which we must adapt. Perhaps it isn’t the hard evidence, the “actual proof,” the experiences of “actual patients” that we truly value. Perhaps value lies elsewhere in the intangible qualities of the brands we live by.

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Read this piece online at: <http://somatosphere.net/forumpost/nostalgia-is-always-about-the-present>

The Generic that is Right for You

Joseph Dumit

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Jeremy Greene's *Generic: The Unbranding of American Medicine* fascinates because the very meaning of the key term "generic" is *so* unstable. Every time the reader thinks they have a handle on its dimensions, another four open up. The main cluster that grabbed me involved the seemingly endless variability in what constitutes a copy of a pill. Beyond the so-called "same active ingredient" (let's call it a molecule for the moment), Greene traces the ways that the "inactive" ingredients, the coating, the processing, and even the look and feel of the pill, all *might* matter for the pill's effectiveness and for its side effects. He also details specific cases where each of these did matter, noting that most of the time they did not. But who can know for sure?

And there's the rub. Who is supposed to know, and who gets to judge that what is claimed to be same is same enough? One of the lines running through *Generic* is the burden of proof. Furthermore, are copies that meet some current standard assumed to be good enough until proven otherwise? And then are they fully substitutable in all cases? Or is it up to the maker of the copy to prove that the pills behave the same in all relevant people – at the limit this means running another full-scale clinical trial.

Greene exquisitely demonstrates how burden of proof is not a technical decision but a thoroughly *business* concept that works socially and politically in the U.S. The profits and growth of industries – big brand Pharma, small and big Generics, as well as insurance companies, HMOs, pharmacy benefits managers, and drugstore chains – are shaped by the time, delays, and costs of proof. Bruno Latour once argued, "Give me a laboratory and I can raise the world." Here we have: Make me use a lab and I will lose a market.

Greene provides us with an historical kaleidoscope of public relations campaigns by all of the above industries that historically repeatedly repositioned the fate of "generics": their destiny as good (because they are "the same but cheaper", the trademark phrase of Dr. Simi and Farmacias Similares in Mexico – a social and political powerhouse I have learned to admire from Cori Hayden's work on generics in Latin America), or their destiny as evil (because copies are dangerous the way that fakes and pirates are dangerous – adding unnecessary risk to your life). How any of us thinks of generics is the product of these public relations.

But Greene complicates this provocative cultural-political semantic line with a clinical biological one: the main reason why the sameness of generics to brand medicine measured one way is often not the same measured clinically is that humans are so variable, as are their so-called diseases (categories that continue to be adjusted, split, and invented). What Greene cannot

do in this book is what he covered so well in previous one (*Prescribing by Numbers*), is explore the difficulty in stabilizing any one mass illness condition with a drug indicated for it. The very attempt to design a clinical trial for a condition affecting millions means creating a broad indication *and* a drug that works in only 1 in 10, or even 1 in 500 sufferers (see also my *Drugs for Life*). Perhaps it is because the efficacy of the branded pills is so hard to just “see” (by doctor or patient or even the FDA), that the question of whether a generic is the same “hard to see” enters the economic field with such political semantic reverberations.

I would love to see Greene explore this question a bit further in a future publication: the relationship between prescribing by numbers and regulating generics by those numbers. Especially, I'm struck by the fact that so much data on specific symptom and illness patterns and treatment practices now exists – electronically – in all of our patient records, yet they are not being used by governments as the giant clinical trial that they are, to figure out what works, for whom, and at what costs. (If we have already been datamined, at least we could be taking less medicine with better health results!). Greene mentions the 1933 book *100 Million Guinea Pigs*, written before electronic patient records were imagined. Now we can make this 200 million clinical trial a reality. I say let it be studied. This may be one solution to the tyranny of choice.

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Read this piece online at: <http://somasphere.net/forumpost/the-generic-that-is-right-for-you>

Generics and their Doppelgängers

Stefan Ecks

University of Edinburgh

Jeremy Greene's *Generic* describes how off-patent medicines have been legislated and regulated in the United States from the 1960s to the early twenty-first century. Greene's brilliant book is the first full-length monograph to trace the history of how Americans think about generics, and it is going to be the key reference for many years to come.

Generic deals mostly with the US case, but also opens a window onto how generics circulate in other markets and jurisdictions, especially in the global South. Attempts at understanding generics in a comparative perspective seem to be haunted by *Doppelgänger* effects: in different times and different places, generics appear to be "the same but not the same" matters of concern. I have never read a book about medicine in the US that produced so many déjà vus with my experiences of medicine in India. Trust and distrust in different manufacturers, legal contestations of what should count as the "same" or "significantly different," and the political leanings of supporters and detractors of cheaper medications, all look weirdly familiar. Even the notion that "there is no such thing as a 'generic' drug" (p. 54), as promoted by US Big Pharma, is an often heard statement of people who market or sell pharmaceuticals in India. Ironically, though, "we don't sell generics" is repeated by people who sell "generics" (to them, they are "brands").

Greene wrestles with these strange cases of recurrence as well: "We *are* constantly repeating our pasts, but what returns is never exactly the same as what came before, only similar" (p. 269). It could be argued that the "we" here is an American "we," not a global "we." The ghostly doubles of Greene's book are the global histories of generics that have, for the most part, not been written yet. Only when these histories are at hand will it be possible to say what is unique about generics in the United States.

For the time being, Greene assumes that the US case is the real thing and not the *Doppelgänger* of events and processes that happened elsewhere. But that off-patent drugs now make up the largest share of all medicines prescribed is not uniquely US American. Nor is it special that lower-priced drugs are used as a kind of private sector solution to rising health care costs. Nor is it peculiar to the US how Big Pharma came up with a myriad of reasons why generics should be treated like perilous counterfeits.

In the chapter on the "global generic," Greene suggests that the US inspired the global politics of equitable access: "Generic drugs emerged locally as a solution to problems of cost and access in health care earlier in the United States than in many other places in the world" (p. 243).

Even the WHO's essential drugs list, first introduced in 1977, was "informed by North American debates" (p. 246), and an American, Daniel Azarnoff, is credited with drafting its early guidelines. To be sure, these statements about US uniqueness are qualified and contextualized, especially when Greene highlights that easy juxtapositions of "big" US-based generics companies and "small" global competitors do not hold (p. 259). But if the US were the true innovators of affordable access to drugs the world over needs to be studied in greater detail.

Greene also argues that the US led the development of the TRIPs agreements under the World Trade Organization (which is probably true), and that forcing India to protect product patents *allowed* the Indian generics industry to flourish (which is probably not true). In my view, the increases of generics exports from India to the US since 1995 cannot be attributed to TRIPs. For example, Dr. Reddy's Laboratories' landmark success in breaking into the US market with its version of fluoxetine 40mg in 2001 rested on its ability to play by much older FDA rules, TRIPs had nothing to do with it. And it seems safe to say that TRIPs has not been a growth engine for generics manufacturers, in India or elsewhere. The vicious legal wrangling around Novartis' Indian patent application for the anti-cancer drug Glivec shows that, if anything, TRIPs is a huge barrier for the global reach of generic manufacturers.

So what is special, or innovative, about US generics? It might be the historical timing of some pieces of legislation. It might be specific assemblages of agencies, industries, and legislators. It might be that prices for patent-protected drugs are even higher in the US than elsewhere, making affordable generics even more alluring. However, none of this means that the US experience paved the way for the rise of the global generic. To me, what makes the global history of generics so intriguing is that the apparent "originals" often come from elsewhere. It was in Tanzania in 1970 that the first essential medicines list was drawn up, for example. Or maybe, when it comes to generics, any questions about a true innovator--of a drug, of a piece of legislation, or of a procurement mechanism—are impossible to answer.

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the specificity of *Generic*

Jeremy Greene
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It is a pleasure to have the opportunity to respond to four careful readings of *Generic* so soon after its publication, especially from four scholars whose work has been so instrumental in shaping the nascent field of pharmaceutical studies. Part of my goal in writing *Generic* was to take a mundane, everyday object (who will ever win a Nobel prize for inventing a generic drug?) and use it to explore the many layers of political contest and social context required to produce the sciences of similarity, laws of substitution, and markets of equivalence which undergird modern biomedical practice. It is deeply gratifying to see these questions engaged on so many different levels of scope and scale.

To research the history of generic drugs is to research a series of controversies which are not merely scientific, political, and economic but also *moral*. As Anne Pollock and Nancy Campbell have captured so well in their comments, generic drugs are frequently glossed

in popular discourse as instruments of vice or virtue but rarely as both. I must confess that I began the research for this book with a sort of tacit preference for the virtuous “little pharma” over the more venal “Big Pharma.” But in the process of researching the history of the generic industry, what emerged (as Pollock so nicely puts it) was a realization not only of the possibility of *immoral* behavior on the part of certain generic manufacturers, but of the *amoral* status of the industry as a whole, neither more nor less likely to engage in graft or collusion than the multinational corporations they were so pluckily arrayed against. The American generic drug industry was encouraged to grow as a private sector solution to a public health problem; the moral practices that have emerged at that intersection are highly ambiguous.

Campbell’s nostalgic reverie for the passing of an era of pharmaceutical branding illustrates another important insight: that the generic drug is a tool for understanding the value of the pharmaceutical brand. It is tempting to see the brand name as a veneer of marketing

plastered awkwardly over an underlying chemical which could be better known by its generic name. That inner, generic drug becomes the *true* drug: it possesses efficacy, safety, pharmacokinetics, pharmacodynamics, all the things one needs to practice medicine. By contrast, the superficial, brand name drug represents everything commercial about biomedicine: advertising budgets, market share, return on investment. The difference between brand and generic seems to recapitulate Marx's distinction between use-value and exchange-value: if the brand-name symbolizes all that is wasteful in commodified, profit-driven healthcare, the generic drug represents medicine at its most useful, affordable, and accessible. Except that it does not. Generic drugs have exchange-values as well, it's just that the nature of that exchange differs between brand-name and generic markets (and, even among different forms of generic drug markets). The generic drug, like the branded drug that came before it, is not a timeless ideal but a dynamic and historically contingent object that emerged at the intersection of key economic and political fault lines in the business and practice of American medicine.

Dumit's comments invite further exploration of this generic specificity. More specifically, he asks what kinds of knowledge is involved in making specific claims about generic medicines, and how generic medicines could in turn be used to produce different kinds of knowledge about different kinds of people. In the course of research for this book I found many kinds of arguments as to why 'generic' was a normative concept that applied to people as well as drugs, and could also be a site of distinction and resistance. If generic drugs worked the same in *most* bodies, did that mean they worked the same in *all* bodies? Or were some kinds of bodies more sensitive to brand-generic difference than others? This question could be asked using a taxonomy of diseases (was the use of a generic beta-blocker during a heart attack more troublesome than in the treatment of high blood pressure?) or of life stages (did the difference in kidney function in geriatric populations raise new concerns for the generic equivalence of renally cleared medicines? What about pediatric formulations?) or by other markers of distinction, including gender, race, and ethnicity. Extending some of Pollock's earlier work on the racialized meanings of generic thiazide diuretics, I found a number of historical alliances between brand-name pharmaceutical manufacturers and minority health groups, who pointed towards the emerging science of pharmacogenetics to argue that—as with other forms of health-related knowledge—sciences of similarity assumed a mainstream white human subject population, and nonwhite patients might have good reason to suspect that they would be more likely to receive substandard care with a cheaper generic drug. These controversies persist today in the guise of pharmacogenomics research.

More recently, patient advocacy groups like the Epilepsy Foundation argue that similarities in brand-generic switching in populations might mask more important differences in small subpopulations of “generic-brittle” patients. Transplant surgeons ask whether higher standards of similarity should be applied to generic immunosuppressants since the costs of losing a transplanted organ are so much higher than the costs of needing to retitrate blood pressure medication. New subdisciplines of pharmacoepidemiology are beginning to study how experience with brand-name and generic drugs play out in real time. In the past decade, the FDA has commissioned a project to link electronic medical records from various public and private health plans into a networked “Sentinel Initiative” to monitor in real-time the safety of drug products. As an exercise in big data and drug experience, the pilot version of this—known as

“mini-Sentinel”—currently represents the lived pharmacological experience of nearly 180 million Americans, which comes pretty close to the 200 million person clinical trial that Dumit calls for.

I am glad that Dumit mentions Cori Hayden's comparative ethnography on generic drugs in North and South America, as I had initially imagined my own research project (an exploration of the many different historical ontologies of the generic drug in the limited geography of the American healthcare system) in conversation with Hayden's (an exploration of the many different local ontologies of the generic drug in the limited time period of the early 21st century) as an example of how historical and ethnographic investigations can work in complement to situate the same (or similar) biomedical object in different dimensions of social context. The potential to foment this line of inquiry is one of the strengths I see in *Somatosphere* more generally: a space for overlaying thick descriptions of science, medicine, and technology using both historical and ethnographic methods.

Yet as Ecks deftly points out in his comments, it is not that easy for historians and anthropologists to simply divvy up the synchronic and the diachronic, the local and the global. It was impossible for me to even begin the story of generic drugs in the United States without also discussing controversies over generic drug naming at the World Health Organization in Geneva; conversely it was impossible for me to close without describing the recent globalization of the generic drug industry and the outsized role that “generic giants” like Ranbaxy and Teva now play in the export economies of countries like India and Israel. What emerges in *Generic*, however, is not a global history of generics, but rather a history that tries to situate US practices in a broader world in which the flow of information and commodities is increasingly more complicated—and more important—to trace.

Ecks is right to caution against reading a diffusionist narrative in this generic history, and though our analysis of the impact of TRIPS may differ, I fully agree with him that there are *many* generic histories not told in this volume, and that these histories are not merely subsequent to some ur-generic-history that took place in the United States, but parallel. Compared to many European countries (and Japan), the US was much earlier to rely on a private generic drug industry to help bring health care costs down—in part because countries like France, Germany, and the UK used the bargaining power of their single-payer health systems to negotiate cheaper prices for brand-name drugs. But alternate histories of generic drugs emerge in places like Brazil, Sri Lanka, Pakistan, and Bangladesh, where generic drug policy supported the development of state-based public generic manufacturers in postwar (and postcolonial) decades—a very different kind of endeavor than the private generic formations in the US. And yet it would also be wrong to think these parallel streams are insulated from one another. As Victor Manuel Garcia has recently described, several of the principal actors responsible for establishing the Colombian generic drug industry were influenced by the generic drug hearings held by Senator Estes Kefauver in 1960, yet generic drug policies in Colombia succeeded where many of Kefauver's initiatives failed. This is not diffusion, but something much more tangled: a complex circulation of concepts and commodities between North and South. Garcia's work on Colombian generic history was featured as part of a panel on at the 4S conference in Buenos Aires this past August highlighting the growing network of scholars working to tell histories of essential medicines across a wide range of pharmaceutical geographies. These histories of

generic pharmaceuticals are multiple and rich in their specificities, and beg for a collective reckoning along questions of ethics, markets, economics, and justice. It is my hope that *Generic*, far from the final word on the subject, will later be read as early effort in this vibrant new area of pharmaceutical studies.

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