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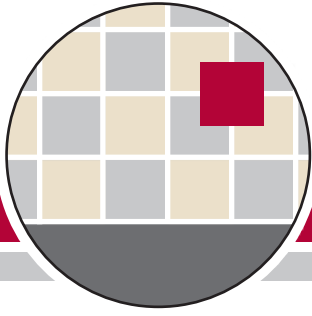
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## GENERIC ENTRY JUJITSU: INNOVATION AND QUALITY IN DRUG MANUFACTURING

*W. Nicholson Price II\**

*The manufacturing side of the pharmaceutical industry has been neglected in innovation theory and policy, with the unfortunate result of stagnant manufacturing techniques driving major problems for the healthcare system. This innovation failure has roots in ineffective intellectual property incentives and high regulatory hurdles to innovative change. Changes in pure regulation or intellectual property incentives have significant potential to help the innovation deficit, but are not the only possibility for change. A relatively minor regulatory change could harness the powerful dynamics of pioneer/generic competition surrounding generic drug market entry. If pioneer firms were permitted to make label claims committing to specific manufacturing quality standards above those required by regulation, generics would need to match those standards to match the pioneer label and win approval. This would create incentives for both pioneers and generics to improving manufacturing control and quality capabilities, ideally leading to a virtuous manufacturing quality arms race with benefits for both the healthcare system and industry itself.*

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Innovation in the pharmaceutical industry is closely studied, but that study has largely missed an important part of the industry: the process of actually manufacturing drugs for distribution and sale. Scholars and lawmakers typically focus on the discovery and development of new drugs, considering the incentives for pioneer manufacturers to develop new drugs,<sup>1</sup> the timing of generic drug entry and various techniques used by pioneer firms to delay that entry,<sup>2</sup> and the impact of regulatory barriers to new drug entry.<sup>3</sup> These are undoubtedly crucial issues in intellectual property and innovation theory, especially since the pharmaceutical industry is exceptional among industries in the importance of patents to driving innovation.<sup>4</sup> However, in an industry centered on innovation, manufacturing is stagnant: some plants have been running continuously for decades with limited upgrades or changes.<sup>5</sup> Old plants have shed metal shavings and glass into drugs,<sup>6</sup> and use few, if any, modern production techniques.<sup>7</sup> The intense focus of scholars and policymakers on drug discovery and market entry has obscured the major innovation deficiency in pharmaceutical manufacturing.

Drug manufacturers across the industry rely on outdated plants and techniques to make their drugs, resulting in expensive and inefficient manufacturing, which frequently fails to guarantee high-quality drug products.<sup>8</sup> Manufacturers have inadequate incentives to invest in innovative, robust ways to manufacture drugs.<sup>9</sup>

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1. See, e.g., Harvey E. Bale, Jr., *Patent Protection and Pharmaceutical Innovation*, 29 N.Y.U. J. INT'L L. & POL. 95 (1996); Christopher M. Holman, *Unpredictability in Patent Law and Its Effect on Pharmaceutical Innovation*, 76 MO. L. REV. 645 (2011).

2. See, e.g., Richard G. Frank & David S. Salkever, *Generic Entry and the Pricing of Pharmaceuticals*, 6 J. ECON. & MGMT. STRATEGY 75 (1997); C. Scott Hemphill & Bhaven N. Sampat, *Evergreening, Patent Challenges, and Effective Market Life in Pharmaceuticals*, 31 J. HEALTH ECON. 327 (2012); Haiden A. Huskamp, Julie M. Donohue, Catherine Koss, Ernst R. Berndt & Richard G. Frank, *Generic Entry, Reformulations, and Promotion of SSRIs*, 26 PHARMACOECONOMICS 603 (2008).

3. Ron A. Bouchard, Jamil Sawani, Chris McLelland, Monika Sawicka & Richard W. Hawkins, *The Pas de Deux of Pharmaceutical Regulation and Innovation: Who's Leading Whom*, 24 BERKELEY TECH. L.J. 1461 (2009); Rebecca S. Eisenberg, *The Role of the FDA in Innovation Policy*, 13 MICH. TELECOMM. & TECH. L. REV. 345 (2006).

4. See, e.g., Benjamin N. Roin, *Unpatentable Drugs and the Standards of Patentability*, 87 TEX. L. REV. 503, 545–56 (2009); Edwin Mansfield, *Patents and Innovation: An Empirical Study*, 32 MGMT. SCI. 173, 173, 175 n.8 (1986).

5. Janet Woodcock & Marta Wosinska, *Economic and Technological Drivers of Generic Sterile Injectable Drug Shortages*, 93 CLINICAL PHARMACOLOGY & THERAPEUTICS 170, 173 (2013).

6. *Id.*

7. See, e.g., THOMAS FRIEDLI ET AL., OPERATIONAL EXCELLENCE IN THE PHARMACEUTICAL INDUSTRY 24–25 (2006); Lawrence X. Yu, *Pharmaceutical Quality by Design: Product and Process Development, Understanding, and Control*, 25 PHARMACEUTICAL RES. 781, 786 (2008).

8. See generally FRIEDLI ET AL., *supra* note 7, at 24–77. Research-oriented pioneer drug companies spend around twice as much on manufacturing drugs as they do on research and development, while generic firms typically spend over half of their revenues on manufacturing expenses. Prabir Basu, Girish Joglekar, Saket Rai, Pradeep Suresh & John Vernon, *Analysis of Manufacturing Costs in Pharmaceutical Companies*, 3 J. PHARMACEUTICAL INNOVATION 30, 33 (2008).

9. See W. Nicholson Price II, *Making Do in Making Drugs: Innovation Policy and Pharmaceutical Manufacturing*, 55 B.C. L. REV. 491, 516–529.

This innovation failure in drug manufacturing results in significant problems for the health care system, including high levels of drug recalls and continuing shortages of essential drugs.<sup>10</sup> 2011 saw the highest number of recalls ever, with over 2300, and 2012, 2010, and 2009 were also in the top four recall years.<sup>11</sup> Most recalls were due to contamination during manufacturing.<sup>12</sup> In a closely linked problem, shortages, including of front-line chemotherapeutics and other essential drugs, frequently occur when plants or production lines shut down to remedy quality problems, or when drugs are recalled and new production cannot fill the demand.<sup>13</sup> The increasing number of shortages affects the vast majority of hospitals, changing care patterns and increasing costs,<sup>14</sup> costing an estimated \$416 million per year.<sup>15</sup>

FDA's direct oversight role can help alleviate the symptoms of the industry's innovation problems, but only in limited ways. FDA can try to reduce quality problems through inspection programs, but its inspection force cannot be everywhere and can only enforce basic safety and efficacy requirements in overseeing manufacturing. Plants are inspected on average only every two and a half years<sup>16</sup>—and that spacing jumps to every seven to thirteen years for overseas plants.<sup>17</sup> Many plants, both domestic and foreign, may never have been inspected.<sup>18</sup>

Shortages are even harder for FDA to address directly. Although FDA can speed inspections, encourage other manufacturers to pick up the slack, or work with firms to resolve problems, ultimately the agency cannot require companies to produce drugs.<sup>19</sup>

The two problems also interact negatively in the context of direct FDA action. Cracking

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10. Barbara K. Gehrett, *A Prescription for Drug Shortages*, 307 JAMA 153, 153 (2012)

11. Bowman Cox, *Contamination, Mix-ups Drive up Drug Recall Totals for 2012*, GOLD SHEET (2013).

12. *Id.*

13. Woodcock & Wosinska, *supra* note 5, at 170–71.

14. Sandra L. Kweder & Susie Dill, *Drug Shortages: The Cycle of Quantity and Quality*, 93 CLINICAL PHARMACOLOGY & THERAPEUTICS 245, 245 (2013) 245 (2013).

15. Shortages cause an estimated \$216 million annual increase in labor costs required to work around shortages. Rola Kaakeh, Burgunda V. Sweet, Cynthia Reilly, Colleen Bush, Sherry DeLoach, Barb Higgins, Angela M. Clark & James Stevenson, *Impact of Drug Shortages on U.S. Health Systems*, 68 AM. J. HEALTH-SYSTEM PHARMACY 1811, 1814 (2011). Increased drug payments and shipping costs total an estimated \$200 million annually. Coleen Cherici, Jerry Frazier, Marv Feldman, Bruce Gordon, Christina A. Petrykiw, Wayne L. Russell & Jay Souza, *Navigating Drug Shortages in American Healthcare: A Premier Healthcare Alliance Analysis*, PREM. INC MARCH (2011).

16. See U.S. GOV'T ACCOUNTABILITY OFFICE, GAO-10-961, DRUG SAFETY: FDA HAS CONDUCTED MORE FOREIGN INSPECTIONS AND BEGUN TO IMPROVE ITS INFORMATION ON FOREIGN ESTABLISHMENTS, BUT MORE PROGRESS IS NEEDED (2010), available at <http://www.gao.gov/products/GAO-10-961> [hereinafter GAO-10-961].

17. U.S. FDA, Fact Sheet: New User Fees for Generic Drugs Will Enhance Americans' Access to Less Expensive Drugs and Generate Major Cost Savings, <http://www.fda.gov/RegulatoryInformation/Legislation/FederalFood-DrugandCosmeticActFDCA/SignificantAmendmentstotheFDCA/FDASIA/ucm310992.htm> (last modified Aug. 17, 2012)

18. See GAO-10-961, *supra* note 16, at 18 (finding that in FY2009, 64% of foreign drugs manufacturing sites and 10% of domestic sites registered with FDA might never have been inspected).

19. Kweder & Dill, *supra* note 14, at 250–51.

down on quality problems helps quality, but may cause shortages by closing plants, either directly or when a company decides that upgrades or repairs necessary to fix quality problems are too expensive to be worthwhile and instead stops production.<sup>20</sup> FDA is required to take potential shortages into account when making regulatory decisions including quality, and may avoid enforcement actions that could result in shortages.<sup>21</sup> Thus, FDA's major enforcement tool for one problem—quality—is hampered by its need to combat another problem—shortages.<sup>22</sup>

More fundamentally, fixing problematic symptoms fails to address the underlying problem: the general absence of innovation in pharmaceutical manufacturing. This innovation deficit has causes rooted both in complex regulatory barriers<sup>23</sup> and in the absence of effective intellectual property incentives.<sup>24</sup> Potential solutions addressing these two sources are important avenues to address this multifaceted problem.<sup>25</sup> However, another important potential avenue for improving innovation and quality is by changing regulatory structures so that market dynamics and competition between firms drives firms to innovate and improve quality.

One such solution, previously proposed, relies on providing more information to consumers and allowing them to shape firm incentives through market mechanisms. FDA officials recently noted that domestic drug purchasers are unlikely to differentiate versions of the same drug based on production quality, which is hard for purchasers to observe.<sup>26</sup> Instead, purchasers typically shop based on cost.<sup>27</sup> This is especially true when purchasers choose among generics, which are supposed to be identical products. Choosing on quality criteria is particularly difficult for drugs like sterile injectables where quality failures may be obscured by other factors. The people who take sterile injectable drugs are frequently quite sick, so problems of drug quality may go uninvestigated as normal complications of the very ill.<sup>28</sup> This manufacturing quality opacity limits market pressure for higher quality manufacturing.

FDA and others have proposed providing quality grades to the market, much like the grades given in some jurisdictions to restaurants or health insurance plans.<sup>29</sup> This approach could influence firm behavior, but the incentives it would create would be indirect, because they would be filtered through the lens of consumer preferences and would depend on consumers expressing manufacturing quality preferences through purchasing decisions. Although consumers are responsive to quality

20. Woodcock & Wosinska, *supra* note 5, at 172–73.

21. Food Drug and Cosmetics Act, 21 U.S.C. § 356D.

22. See Woodcock & Wosinska, *supra* note 5, at 172.

23. See Price II, *supra* note 9, at 510–522.

24. See *id.* at 522–539.

25. See *id.* at 540–561 (proposing reforms to lower regulatory barriers, change intra-firm incentives through altered regulatory regimes, and provide more effective intellectual property incentives through regulatory mechanisms).

26. Woodcock & Wosinska, *supra* note 5, at 171–72.

27. *Id.*

28. *Id.* at 172.

29. *Id.* at 175; Stuart O. Schweitzer, *How the US Food and Drug Administration Can Solve the Prescription Drug Shortage Problem*, 103 AM. J. PUB. HEALTH e10, e12–e13 (2013).

signals in some other contexts,<sup>30</sup> consumerism as a mechanism of quality control faces significant problems in healthcare.<sup>31</sup> A 2000 Kaiser Family Foundation study found that only 12% of patients had used quality information to choose among hospitals, doctors, and health plans; government agencies were ranked far below doctors, family, or friends.<sup>32</sup> For drugs they already have the quality signal of FDA approval to continue manufacturing, an absolute up-or-down signal, which could easily dominate comparatively minor quality gradations. In addition, the fragmented nature of pharmaceuticals' "consumer," made up of insurers, prescribers, and patients, could hinder responses to quality signals due to the difficulty of accurately transmitting and valuing preferences among different entities. In some cases, like injectable drugs, which are purchased by hospitals, any consumer-directed packaging indications of manufacturing quality may be visible only to the purchasing hospital and not to the patient or care provider.

However, consumer preferences are not the only source of market competition. The pharmaceutical industry focuses intensely on the timing and mechanics of generic entry into the market, when the pioneer company's monopoly on a drug is opened to competition. Upon generic entry, the pioneer company typically loses market share quite rapidly, and the prices consumers pay sharply decrease.<sup>33</sup> Pioneer companies engage in several distinct strategic behaviors to try to delay the entry of generic firms, including "evergreening" strategies to extend patent protection<sup>34</sup> and reverse-payment settlements where pioneer firms pay generic firms to delay entering the market.<sup>35</sup>

30. Schweitzer, *supra* note 29, at e13.

31. See Carl E. Schneider & Mark A. Hall, *The Patient Life: Can Consumers Direct Health Care?*, 35 AM. J.L. & MED. 7, 48–59 (2009) (noting the difficulties of healthcare consumerism, even assuming accurate and trustworthy information is both provided to and understood by consumers); see also I. Glenn Cohen, *Protecting Patients with Passports: Medical Tourism and the Patient-Protective Argument*, 95 IOWA L. REV. 1467, 1509–10 (2010) (reviewing literature on problems with information provision as a mechanism of quality control in healthcare).

32. THE KAISER FAMILY FOUND./AGENCY FOR HEALTH CARE RESEARCH & QUALITY, NATIONAL SURVEY ON AMERICANS AS HEALTH CARE CONSUMERS: AN UPDATE ON THE ROLE OF QUALITY INFORMATION (2000), Charts 10–12, 17 available at <http://www.ahrq.gov/downloads/pub/kffchartbk00.pdf>.

33. Notably, a drug's average price decrease is largely due to lower prices for generics; the price of the brand-name drug manufactured by the pioneer company typically remains high, in a pattern of market segregation as opposed to pure commodity competition. Frank & Salkever, *supra* note 2, at 82–85, 89–90.

34. Patent evergreening strategies include obtaining patents on new crystal forms of existing drugs, single enantiomers (left- or right-“handed” versions of molecules rather than a mixture of the two), new formulations (for instance, changing from a tablet to a capsule), or drug combinations, among others. Brian Whitehead, Stuart Jackson & Richard Kempner, *Managing Generic Competition and Patent Strategies in the Pharmaceutical Industry*, 3 J. INTELL. PROP. L. PRAC. 226, 227–29 (2008). For an examination of several strategies for maintaining market exclusivity in the context of a popular class of antidepressants, see Huskamp et al., *supra* note 2. For an empirical study of the effectiveness of such strategies, see Hemphill & Sampat, *supra* note 2.

35. In reverse-payment settlements, pioneer companies pay generic companies to delay market entry in the context of a patent infringement suit. These settlements were recently considered by the Supreme Court in *F.T.C. v. Actavis, Inc.*, 133 S. Ct. 2223 (2013) and have been the subject of much scholarly attention. See, e.g., Lisa Allen, *Reviewing the Legality of Pharmaceutical Reverse Payment Settlements: The FTC Doesn't Get It Right*, 8 GEO. J.L. & PUB. POL'Y 245 (2010); Daniel A. Crane, *Per Se Illegality for Reverse Payment Patent Settlements?*, 61 ALA. L. REV. 575 (2010); Ronald W. Davis, *Reverse Payment Patent Settlements: A View into the Abyss, and a Modest Proposal*,

Altering the possible behavior of firms within the dynamic of generic entry could provide a novel and potentially more powerful incentive to drive firms to increase manufacturing quality. FDA could seek to tie quality improvement to a key point in the drug lifecycle: the market entry of generic drugs after patent expiration. If a branded-drug manufacturer proposed manufacturing quality commitments that would be included in the drug label, the legal requirement that generics use an identical label, and hence commit to identical quality standards, could provide incentives for manufacturing innovation in both brand and generic companies. For instance, a manufacturer could make a voluntary commitment to ensure that the amount of active pharmaceutical ingredient would vary no more than +/- 2% from the stated amount, rather than the +/- 10% generally allowed today.<sup>36</sup> The manufacturer would need to demonstrate its compliance capability for the commitment to be included on the label. For a generic to be approved, the generic's maker would be required to demonstrate and commit to the higher level of manufacturing quality.

This approach creates incentives for both branded and generic manufacturers to increase manufacturing quality. Branded-drug manufacturers create higher entry barriers for generics, which may prolong the period of monopoly pricing and may decrease the number of eventual generic entrants. However, to obtain this benefit, branded-drug makers must invest in higher-quality manufacturing. Generic companies, to avoid exclusion from the market, must similarly invest. Higher quality manufacturing in both sectors will have significant consumer benefits: reductions in recalls, contamination events, and drug shortages, as well as other more speculative potential benefits of having more precisely manufactured drugs, such as reduced dosage variation.

Because generics will still compete on price, firms will have incentives to innovate to increase quality while still keeping costs low. As the automotive, electronics, and other industries have demonstrated, production costs can decrease with better-controlled manufacturing even while quality increases.<sup>37</sup> This dual-goal incentive contrasts with the current potential for “races to the bottom” in which quality can be sacrificed for the sake of cutting costs, as has been observed in outsourced drug manufacturing.<sup>38</sup>

The goal of the proposed incentive mechanism is to spur a “race to the top,” in which manu-

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21 ANTITRUST 26 (2006); Catherine J.K. Sandoval, *Pharmaceutical Reverse Payment Settlements: Presumptions, Procedural Burdens, and Covenants Not to Sue Generic Drug Manufacturers*, 26 SANTA CLARA COMPUTER HIGH TECH. L.J. 141 (2010).

36. See, e.g., U.S. FDA, GUIDANCE FOR INDUSTRY: INVESTIGATING OUT-OF-SPECIFICATION (OOS) TEST RESULTS FOR PHARMACEUTICAL PRODUCTION, 11 (2006), available at [www.fda.gov/downloads/Drugs/Guidances/ucm070287.pdf](http://www.fda.gov/downloads/Drugs/Guidances/ucm070287.pdf) (allowing 10% deviations).

37. See, e.g., George Byrne, Dave Lubowe & Amy Blitz, *Using a Lean Six Sigma Approach to Drive Innovation*, 35 STRATEGY & LEADERSHIP 5 (2007) (case study of cost and quality improvements for Caterpillar equipment manufacturing); M. Soković, D. Pavletić & E. Krulčić, *Six Sigma Process Improvements in Automotive Parts Production*, 19 J. ACHIEVEMENTS MATERIALS & MANUFACTURING ENGINEERING 96, 100 (2006) (case study of automotive part plant innovation resulting in higher quality and lower costs).

38. John V. Gray, Aleda V. Roth & Michael J. Leiblein, *Quality Risk in Offshore Manufacturing: Evidence from the Pharmaceutical Industry*, 29 J. OPERATIONS MGMT. 737, 745–48 (2011).

facturers continually innovate to increase quality, and generics follow close behind to match quality and decrease manufacturing costs. In the process, innovation, robustness of manufacturing processes, and quality should increase across the industry.

The principal concern with this approach is that limits on generic entry will increase average prices and decrease patient access, which weighs against any benefits from higher quality manufacturing. At least some decreased generic entry, whether through delay or fewer entrants, is an inherent part of this mechanism; without such a decrease, there is no incentive for brand manufacturers to commit to higher quality. However, price increases—at least temporary ones—are the unfortunate but likely result of any proposal for increased quality that imposes costs on industry or offers incentives.<sup>39</sup> Nonetheless, to the extent that “races to the top” are actually races, delays to generic entry are likely to shrink over time as generic firms become more innovative and flexible and can more easily match quality requirements. Similarly, once generic entry does occur, higher quality manufacturing will not necessarily result in higher marginal costs and prices, as demonstrated by the experience of other industries, where consumer products, electronics, and cars are all manufactured to higher quality without significantly increased costs as a result of manufacturing innovation. In the longer term, some prices might even decrease as manufacturing becomes more robust and eventually less expensive.

A related concern is that branded-drug makers might game the system. For instance, manufacturers might try to constantly add new requirements to keep pushing back generic entry. FDA could serve as a gatekeeper to address this problem by prohibiting serial quality commitments or requiring that such later additions be substantial.<sup>40</sup> Alternately, manufacturers might commit to unnecessarily stringent quality conditions: investments that do not yield clinical benefits but make manufacturing prohibitively difficult or costly to restrain generic entry. FDA gatekeeping could similarly address this issue by ensuring that quality commitments are meaningful. However, even some quality standards without immediate clinical relevance, like reduced dosage variation in a drug, which operates similarly and safely across a relatively wide range of dosages, could still promote more robust and controlled manufacturing, which may have broader collateral benefits in other problem areas like contamination.

More broadly, branded-drug manufacturers already have and energetically use tools to limit generic entry, but those tools generally do not improve manufacturing quality to benefit consumers. For example, manufacturers can already pursue unusual drug specifications or challenging formulations, which are hard for generics to match and manufacture; empirically, fewer generics compete for difficult-to-manufacture products.<sup>41</sup> But these approaches generally come without consumer benefits, and fail to incentivize meaningful innovation. Allowing a similar mechanism for label-based com-

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39. Gehrett, *supra* note 10, at 154

40. A similar requirement exists today for biologics; after the first period of biologic market exclusivity, subsequent periods of exclusivity are unavailable for changes in formulation, indication, or strength, or for changes to the biologic, which do not change its safety, purity, or potency. 42 U.S.C. § 262(k)(7)(C) (2013).

41. C. Scott Hemphill & Bhaven N. Sampat, *When Do Generics Challenge Drug Patents?*, 8 J. EMPIRICAL LEGAL STUD. 613, 632–33 (2011).



mitments to quality could drive innovation in manufacturing processes, resulting in tangible benefits to patients, providers, and the industry.

This limited proposal is far from a panacea for the problems in drug manufacturing; many other factors are involved, including intellectual property incentives, industry culture, and regulatory barriers to innovative change, and other policy changes will be required as part of an overall solution.<sup>42</sup> However, creating a way for improved quality to be valuable, not just to consumers, but also to drug companies, would be a step in the right direction.

Outside the context of drug manufacturing, this proposal adds to the quiver of possible innovation drivers. Many innovation incentives rely on providing extra rewards to innovative actors, whether those rewards come in the form of exclusivity, grants, tax rebates, or otherwise. This proposal suggests harnessing intra-industry competition regarding an existing reward—altering the timing of generic market entry—to drive innovation without significant external inputs. While there may be implementation problems not considered in depth in this Essay, using an industry’s procedural creativity to drive substantive innovation offers an enticing possibility for change.

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42. For a broader treatment of problems in drug manufacturing generally, see Price II, *supra* note 9.