Federal Communications Commission

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[1] The Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 301 . (2011), as amended by the Drug Price Competition and Patent Term Restoration Act of 1984, Public Law 98–417, 98 Stat. 1585 (codified as amended in scattered sections of 21 & 35 U.S.C.) (known as Hatch-Waxman), and the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Public Law 108–173, § 1112, 117 Stat. 2066, 2461–63 (codified at 21 U.S.C. 355).

[2] *P :* , Health Affairs 1 (Oct. 10, 2013), ://. / / / _ / _ *100.* (''[Biologics] account for a substantial and increasing share of the pharmaceutical market and a growing share of health care costs'').

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6 ; IMS Institute for Healthcare Informatics, IMS Health, The Use of Medicines in the United States: Review of 2011 (2012), :// . / / / / %20 %20 % 20 %20 / _ _ . _ _2011. [hereinafter IMS, Use of Medicines]; IMS Institute for Healthcare Informatics, IMS Health, Generic Drug Savings in the U.S.: Savings $1 Trillion Over 10 Years 2 (4th ed. 2012), :// . / / / 2012 . (Study commissioned by GPhA) (''Current biologic medicine costs are staggering, putting these lifesaving treatments out of reach for many patients. Even after insurance coverage, co-pays can be thousands of dollars each year. A Congressional Research Service (CRS) study completed in 2010 showed that the cost of biologics is often prohibitively high, both for patients and the government. The report found that average annual costs for the rheumatoid arthritis treatment Enbrel® was $26,000, Herceptin® for breast cancer averaged $37,000, Humira® for Crohn's disease was more than $51,000 per year, and the annual cost for Cerezyme® to treat Gaucher's disease was $200,000.''); Andrew Pollack, , , N.Y. Times (Jan. 28, 2013), :// . . / 2013/01/29/ / - - - - - 0.

7 IMS, Use of Medicines, supra note 6, at 27; Staff of Comm. on Health Policy, Fla. S., 2013 Session, Bill Analysis and Fiscal Impact Statement, CS/SB 732, at 3, (2013), :// . . / / /2013/0732/ / 94 4 3 P %7 14/ P / /0700-0799/0732/ / 2013 0732. .P ; Cong. Budget Office, Congressional Budget Office Cost Estimate: S. 1695 Biologics Price Competition and Innovation Act of 2007, at 5 (2008), :// . . / / / / / / /94 / 9496/ 1695. [hereinafter CBO Report] (''In recent years, total spending on biologics has grown rapidly, with nominal spending growth averaging roughly between 15 percent and 20 percent annually; spending amounted to about $40 billion in 2006. . . . We estimate that by 2018 about $70 billion in national spending on biologics could face competition by FOBs . . . .'').

products.[18] Under the BPCIA, a ''biosimilar'' product is ''highly similar to the reference product notwithstanding minor differences in clinically inactive components,'' and ''there are no clinically meaningful differences between the biological product and the [FDA-licensed biological] reference product in terms of safety, purity, and potency of the product.'' [19] The BPCIA requirements for an ''interchangeable'' biologic product are more stringent. An interchangeable biologic product is expected to produce the same clinical result as the FDA-licensed biological reference product in any given patient. Furthermore, for a product administered more than once, the safety and reduced efficacy risks of switching from the reference drug to an interchangeable drug, or alternating between the reference drug and an interchangeable drug, cannot be greater than the risks posed by use of the reference product without alternating or switching.[20]

BPCIA provides that interchangeable biologics ''may be substituted for the reference biologic without the intervention of the health care provider who prescribed the reference product.'' [21] It does not address substitution of non-interchangeable biosimilars. The FDA is authorized to issue regulations that define the requirements for applicants claiming ''interchangeability'' or ''biosimilar'' status, but the agency has not finalized guidelines on these issues.[22]

In 2009, the Commission issued a report, [illegible] (''FTC FOB Report''),[23] which discussed the results of its November 21, 2008 workshop to examine ''whether the price of biologics might be reduced by competition if there were a statutory process to encourage [FOBs] to enter and compete with pioneer biologics once a pioneer drug's patents have expired.'' [24] In its report, the Commission noted that the scientific differences between biologic and small-molecule drug products would complicate efforts to devise an approval process for FOBs.[25] Biologics are often three-dimensional folded proteins, derived from living matter or manufactured within living cells using recombinant DNA biotechnologies.[26] They are generally more complex and immunogenic, and more complex to manufacture, than traditional small-molecule drugs.[27]

[18] 42 U.S.C. 262(k) (2011).

[19] § 262(i)(2).

[20] § 262(i)(3).

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[22] On February 9, 2013, the FDA issued three draft guidance documents regarding Scientific Considerations, Quality Considerations, and Q&As, and solicited public comments for the draft guidance documents; the public comment period has now closed. No final guidance documents have yet been issued. The Draft Guidance included: (1) ''Scientific Considerations in Demonstrating Biosimilarity to a Reference Product;'' (2) ''Quality Considerations in Demonstrating Biosimilarity to a Reference Protein Product;'' and (3) ''Guidance for Industry on Biosimilars: Q & As Regarding Implementation of the BPCI Act of 2009.'' [illegible], U.S. Food & Drug Admin., U.S. Dept. of Health & Human Servs., [illegible] *291186.* (last updated Feb. 9, 2012); [illegible] *291197.* (last updated Feb. 9, 2012).

[23] Press Release, Fed. Trade Comm'n, FTC Releases Report on ''Follow-on Biologic Drug Competition'': Providing FDA With Authority to Approve Follow-on Biologics Would be an Efficient Way to Bring Them to Market, Lowering Consumers' Health Care Costs (June 10, 2009), [illegible] *2_110309.*

[24] FTC FOB Report, note 11, exec. summ. at i.

[25] . exec. summ. at ii.

[26] . at 8–9.

[27] A biologic drug is ''immunogenic'' if it stimulates an immune response in the patient; this can raise safety and efficacy concerns. Letter from Frank M. Torti, Principal Deputy Comm'r & Chief Scientist, U.S. Food & Drug Admin., to Frank Pallone, Jr., Chairman, H. Subcomm. on Health 1 (Sept. 18, 2008), [illegible] [illegible], note 2, at 1. Steven Kozlowski, Janet Woodcock, Karen Midthun & Rachel Behrman Sherman, [illegible], 365 New Eng. J. Med. 385, 386 (2011), [illegible] (''additional animal and clinical studies will generally be needed for protein biosimilars for the foreseeable future, the scope and extent of such studies may be reduced further if more extensive fingerprint-like characterization is used.'').

[30] FTC FOB Report, note 11, at 12; Mandy Jackson, [illegible] *2015,* [illegible], July 5, 2013; Henry Grabowski et al., [illegible], 41 Seton Hall L. Rev. 511 (2011); Editorial, [illegible], 31 Nature Biotech. 264 (2013), [illegible] *.2550.* .

[31] The workshop proposed in this notice will consider whether new facts require revisions to the Commission's prior predictions.

[32] FTC FOB Report, note 11, exec. summ. at v; CBO Report, note 7, at 5.

[33] The CBO predicted that the BCPIA, if enacted, would ''reduce total expenditures on biologics in the United States by $0.2 billion over the 2009–2013 period and by about $25 billion over the 2009–2018 period.'' CBO Report, note 7, at 1.

[34] Thomas M. Burton & Jonathan D. Rockoff, [illegible], Wall St. J., Feb. 10, 2012, [illegible] *10001424052970204642604577213143424515820.*

[35] Steven Kozlowski, Director, Office of Biotechnology Products, U.S. Food & Drug Admin., Remarks at 11th EGA International Symposium on Biosimilar Medicines: U.S. FDA Perspectives on Biosimilar Development and Approval (April 26, 2013). Whether any applications have been filed with the FDA is not public.

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36 Drug Product Selection, note 12, at 1.

37 . at 1.

38 In sum, the FTC Staff Report concluded that (1) ''antisubstitution laws impose substantial unwarranted costs on consumers by unduly restricting price competition in the multisource prescription drug market;'' and (2) repeal of antisubstitution laws would ''produce significant consumer benefits without compromising the quality of health care.'' . To remedy the situation and facilitate pharmacists' use of therapeutically equivalent, but less expensive generic drugs, the FTC Staff recommended that the states adopt a Model Drug Product Selection Act. . at 1.

39 FDA Approved Drug Products with Therapeutic Equivalence Evaluations preface at iv (33rd ed. 2013), :// . . / / / / / *071436*. .