116TH CONGRESS
2d Session
HOUSE OF REPRESENTATIVES
REPORT
116–694

STOP SIGNIFICANT AND TIME-WASTING ABUSE LIMITING LEGITIMATE INNOVATION OF NEW GENERICS ACT

DECEMBER 24, 2020.—Committed to the Committee of the Whole House on the State of the Union and ordered to be printed

Mr. NADLER, from the Committee on the Judiciary, submitted the following

R E P O R T

[To accompany H.R. 2374]

[Including cost estimate of the Congressional Budget Office]

The Committee on the Judiciary, to whom was referred the bill (H.R. 2374) to enable the Federal Trade Commission to deter filing of sham citizen petitions to cover an attempt to interfere with approval of a competing generic drug or biosimilar, to foster competition and facilitate the efficient review of petitions filed in good faith to raise legitimate public heath concerns, and for other purposes, having considered the same, reports favorably thereon without amendment and recommends that the bill do pass.

CONTENTS

Purpose and Summary

H.R. 2374, the "Stop Significant and Time-wasting Abuse Limiting Legitimate Innovation of New Generics Act," or the "Stop STALLING Act," is designed to address the soaring cost of pre-

scription drugs by targeting misuse of the citizen petition process at the Food and Drug Administration (FDA) to block generic competitors from entering the market. The Stop STALLING Act establishes that the submission of objectively baseless citizen petitions to prevent or delay the approval of a covered drug product—sham petitions—is an unfair method of competition under section 5 of the Federal Trade Commission (FTC) Act. Furthermore, the legislation establishes that a petition is presumptively illegal when the Secretary of Health and Human Services determines that the petition was submitted with the primary purpose of delaying approval of a new drug, along with meeting additional criteria. H.R. 2374 is supported by a coalition of healthcare providers and public-interest organizations including Consumer Reports, Patients for Affordable Drugs Now, and Premier Inc., Healthcare Alliance.

Background and Need for the Legislation

The FDA's citizen petition procedures were established to provide concerned citizens with an opportunity to solicit agency action regarding health and safety policy.[1] The process, which is open to anyone, allows individuals to request that the FDA "issue, amend, or revoke a regulation, or order or take or refrain from taking any other form of administrative action."[2]

While various entities have used the citizen petition process to raise a variety of necessary health and safety issues, certain brand-name drug manufacturers have manipulated the process to stifle generic competition. For example, some branded manufacturers have responded to applications for drug approval by generic competitors by filing citizen petitions that question the safety, efficacy, and bioequivalence standards for approving generic drugs.[3] Because the FDA must review and respond to every citizen petition it receives, including supplements or amendments to petitions,[4] makers of generic drugs accordingly report that unwarranted petitions may cause manufacturing stoppages or significant delays in the FDA approval process.[5] Studies have concluded that while these petitions often lack merit, they can be very effective at delaying the entry of lower-cost generic competitors.[6] According to the FTC, abuse of this system allows some drug companies to unlawfully maintain a monopoly by delaying generic entry.[7] For example,

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[1] *See, e.g.,* 21 C.F.R. § 10.30(b)(3) (2019).

[2] *Id.*

[3] *See, e.g., In re* Flonase Antitrust Litig., 795 F. Supp. 2d 300 (E.D. Pa. 2011) (brand-name manufacturer filed citizen petitions requesting that the FDA issue final guidance and impose more stringent testing standards before approving any abbreviated new drug applications (ANDAs)); La. Wholesale Drug Co. v. Sanofi-Aventis, No. 07–cv–7343, 2009 WL 2708110 (S.D.N.Y. Aug. 28, 2009) (brand-name manufacturer filed citizen petition requesting that the FDA require certain bioequivalence studies before approving any ANDA filed for a competing generic drug).

[4] 21 C.F.R. § 10.30(e)(1)–(2), (g)(2019).

[5] *See, e.g., In re* Flonase, 795 F. Supp. 2d at 302.

[6] *See, e.g.,* Michael A. Carrier & Carl Minniti, *Citizen Petitions: Long, Late-Filed, and At-Last Denied,* 66 AM. UNIV. L. REV. 305, 352 (2016) (finding that the FDA denied "more than 9 out of every 10 petitions" filed between 2011 and 2015 and that citizen petitions "play an increasingly important role in delaying generic competition").

[7] *See, e.g.,* Press Release, Fed. Trade Comm'n, FTC Submits Comment on FDA Guidance Aimed at Deterring Abuse of Citizen Petition Process (Dec. 4, 2018) (stating that the "FTC has investigated complaints of citizen petition abuse as potential violations of federal antitrust law" and that "[i]n 2017, the agency filed a complaint in federal district court charging that branded pharmaceutical company Shire ViroPharma illegally maintained its monopoly power by abusing . . . the citizen petition process"), https://www.ftc.gov/news-events/press-releases/2018/12/ftc-submits-comment-fda-guidance-aimed-deterring-abuse-citizen.

this abusive tactic has allegedly been used to delay life-saving treatments for opioid addiction and gastrointestinal infections.[8]

Leading healthcare experts also agree that sham petitions are a significant driver of high prescription drug prices. Dr. Aaron Kesselheim of Harvard Medical School testified last Congress that this abusive conduct can "substantially delay[] entry of a more affordable generic product."[9] Professor Robin Feldman of the University of California at Hastings also found "empirical evidence that the citizen petition process at the FDA has become a key avenue for strategic behavior by pharmaceutical companies to delay entry of generic competition."[10] Several witnesses discussed this problem at a Subcommittee on Antitrust, Commercial, and Administrative Law hearing this Congress.[11]

Congress previously attempted to stem the abuse of the FDA's citizen petition process. In 2007, Congress amended the Federal Food, Drug, and Cosmetic Act (FDCA) to help prevent citizen petitions from being used to delay generic entry.[12] The 2007 amendments authorized new regulations and required the FDA to respond to citizen petitions concerning generic applications within 180 days (shortened to 150 days in 2012);[13] required that petition filers certify the petition's submission was not intentionally delayed; and authorized the FDA to summarily deny such petitions in certain circumstances.[14]

Although imposing a 150-day deadline for the FDA to respond may have reduced the length of delay, it—and other changes described above—have arguably failed with respect to deterring the behavior. The FDA recently reported to Congress that it "continues to be concerned that section 505(q) does not discourage the submission of petitions that are intended primarily to delay the approval of competing drug products and do not raise valid scientific issues."[15] In support of this concern, based on data available in 2017, then-FDA Commissioner Scott Gottlieb suggested that the imposition of the 150-day deadline "had limited impact in discour-

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[8] *See* Complaint, Fed. Trade Comm'n v. Shire ViroPharma, Inc., No. 17–cv–0131 (D. Del. Feb. 7, 2017), https://www.ftc.gov/system/files/documents/cases/170216viropharma_unredacted_sealed_complaint_.pdf; Complaint, Wisconsin v. Indivior, Inc., No. 16–cv–5072 (E.D. Pa. Sept. 22, 2016).

[9] *Examining the Actions of Drug Companies in Raising Prescription Drug Prices: Hearing Before the H. Comm. on Oversight and Reform*, 116th Cong. (2019) (written testimony of Aaron S. Kesselheim, Associate Professor of Medicine, Harvard Medical School, at 8), https://docs.house.gov/meetings/GO/GO00/20190129/108817/HHRG-116-GO00-Wstate-KesselheimA-20190129.pdf.

[10] Robin Feldman et al., *Empirical Evidence of Drug Companies Using Citizen Petitions To Hold Off Competition* (Univ. Cal. Hastings Research Paper No. 269, Feb. 14, 2018).

[11] *Diagnosing the Problem: Exploring the Effects of Consolidation and Anticompetitive Conduct in Health Care Markets: Hearing Before the Subcomm. on Antitrust, Commercial, and Admin. Law of the H. Comm. on the Judiciary,* 116th Cong. (2019); *see also Antitrust Concerns and the FDA Approval Process: Hearing Before the Subcomm. on Regulatory Reform, Commercial, and Antitrust Law of the H. Comm. on the Judiciary,* 115th Cong. (2017) (written testimony of Scott Gottlieb, Commissioner of Food and Drugs, Food and Drug Administration, at 2, 8–10), https://docs.house.gov/meetings/JU/JU05/20170727/106333/HHRG-115-JU05-Wstate-GottliebS-20170727.pdf.

[12] *See* Food and Drug Administration Amendments Act of 2007, Pub. L. No. 110–85, § 914, 21 Stat. 823 (codified as amended at 21 U.S.C. § 355(q) (2018)).

[13] *See* Food and Drug Administration Safety and Innovation Act, Pub. L. No. 112–144, § 1135, 126 Stat. 993 (codified as amended at 21 U.S.C. § 355(q) (2018)).

[14] *See* Food and Drug Administration Amendments Act of 2007, Pub. L. No. 110–85, § 914, 21 Stat. 823 (codified as amended at 21 U.S.C. § 355(q) (2018)).

[15] U.S. FOOD & DRUG ADMIN., TWELFTH ANNUAL REPORT ON DELAYS IN APPROVALS OF APPLICATIONS RELATED TO CITIZEN PETITIONS AND PETITIONS FOR STAY OF AGENCY ACTION FOR FISCAL YEAR 2019, at 1, 5 (2020), https://www.fda.gov/media/143518/download.

aging the submission of petitions intended primarily to block or delay generic competition."[16]

The FTC has also tried to address the problem of sham citizen petitions. In 2017, the FTC filed a complaint alleging that Shire ViroPharma Inc. abused the citizen petition process to illegally maintain a monopoly on Vancocin Capsules, a drug used to treat a potentially life-threatening gastrointestinal infection.[17] According to the FTC, "[f]acing the threat of generic competition to its lucrative franchise, ViroPharma inundated the FDA with regulatory and court filings—forty-six in all—to delay the FDA's approval of generic Vancocin Capsules."[18] The FTC complaint further states that these "repetitive, serial, and meritless filings lacked any supporting clinical data," but, nonetheless, "succeeded in delaying generic entry at a cost of hundreds of millions of dollars to patients and other purchasers."[19]

On March 20, 2018, the district court dismissed the complaint and, according to the FTC's appellate brief, "held that no matter how egregious a defendant's past violation, the FTC cannot sue to enforce [section 13 of] the FTC Act unless it alleges facts showing that a further violation is not just reasonably likely but imminent."[20] On appeal, the Third Circuit Court of Appeals affirmed the district court's order of dismissal.[21] The courts' narrow reading of section 13(b) could make it harder for the FTC to address wrongdoing by drug companies that have filed sham petitions. Notably, neither the district court nor the court of appeals reached the merits of whether ViroPharma's conduct violated antitrust law beyond the district court finding that the allegations, taken as true, were sufficient to overcome the *Noerr-Pennington* presumption of antitrust immunity for government petitions.[22]

The Stop STALLING Act seeks to end abuse of the citizen petition process by establishing that, under certain circumstances, using sham petitions to block generic competition is presumptively illegal under the FTC Act. H.R. 2374 strengthens the FTC's ability to challenge citizen petition abuse in court, striking the right balance by deterring anti-competitive delays while protecting the legitimate use of citizen petitions.

Hearings

In the 116th Congress, the Subcommittee on Antitrust, Commercial, and Administrative Law held a hearing on "Diagnosing the Problem: Exploring the Effects of Consolidation and Anticompeti-

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[16] *Antitrust Concerns and the FDA Approval Process: Hearing Before the Subcomm. on Regulatory Reform, Commercial, and Admin. Law of the H. Comm. on the Judiciary,* 115th Cong. 10 (2017) (written testimony of Scott Gottlieb, Commissioner of Food and Drugs, Food and Drug Administration), https://docs.house.gov/meetings/JU/JU05/20170727/106333/HHRG-115-JU05-Wstate-GottliebS-20170727.pdf.

[17] Complaint, Fed. Trade Comm'n v. Shire ViroPharma, Inc., No. 17–cv–0131 (D. Del. dismissed Mar. 20, 2018), *aff'd*, 917 F.3d 147 (3d Cir. 2019), https://www.ftc.gov/system/files/documents/cases/170216viropharma_unredacted_sealed_complaint_.pdf.

[18] *Id.* at ¶1.

[19] *Id.*

[20] Brief for Plaintiff-Appellant at 2, Fed. Trade Comm'n v. Shire ViroPharma, Inc., 917 F.3d 147 (3rd Cir. 2019) (No. 18–1807), https://www.ftc.gov/system/files/documents/cases/shire_viropharma_inc_ftc_opening_brief_and_appendix_vol_1_6-19-18.pdf.

[21] Fed. Trade Comm'n v. Shire ViroPharma, Inc., 917 F.3d 147 (3rd Cir. 2019).

[22] Fed. Trade Comm'n v. Shire ViroPharma Inc., No. CV 17–131–RGA, 2018 WL 1401329, at *7 (D. Del. Mar. 20, 2018), aff'd, 917 F.3d 147 (3d Cir. 2019).

tive Conduct in Health Care Markets."[23] At this hearing, several witnesses testified about competition issues in health care markets, including Dr. Fiona Scott Morton, Professor of Economics at Yale School of Management; Dr. Martin Gaynor, Professor of Economics and Health Policy at Carnegie Mellon University; Michael Kades, Director of Markets and Competition Policy at Washington Center for Equitable Growth; and Dr. Craig Garthwaite, Herman R. Smith Research Professor at Northwestern University's Kellogg School of Management. Professor Scott Morton, Professor Garthwaite, and Mr. Kades mentioned or highlighted citizen petition abuse as a problematic anti-competitive business practice and testified about the need for Congress to address the issue.[24] This hearing satisfies the requirement of H. Res. 6, sec. 103(i).

In the 115th Congress, the Subcommittee on Regulatory Reform, Commercial, and Antitrust Law held a two-paneled hearing on "Antitrust Concerns and the FDA Approval Process."[25] On the first panel, the Subcommittee heard testimony from Dr. Scott Gottlieb, M.D., Commissioner of the FDA, and Markus Meier, Acting Director, Bureau of Competition at the FTC. On the second panel, the Subcommittee heard testimony from Professor David Olson, Boston College Law School; Professor Erika Lietzan, University of Missouri School of Law; Alden Abbott, Deputy Director and Senior Legal Fellow, the Heritage Foundation; and Professor Aaron Kesselheim, M.D., M.P.H., Harvard Medical School. At the hearing, Messrs. Meier and Abbott, and Dr. Kesselheim testified that citizen petition abuse remains a problem in need of congressional attention.[26]

Committee Consideration

On April 30, 2019, the Committee met in open session and ordered the bill, H.R. 2374, favorably reported, without amendment, by voice vote, a quorum being present.

Committee Votes

In compliance with clause 3(b) of rule XIII of the Rules of the House of Representatives, the Committee advises that no rollcall votes occurred during the Committee's consideration of H.R. 2374.

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[23] *Diagnosing the Problem: Exploring the Effects of Consolidation and Anticompetitive Conduct in Health Care Markets: Hearing Before the Subcomm. on Antitrust, Commercial, and Admin. Law of the H. Comm. on the Judiciary,* 116th Cong. (2019).

[24] *Id.* (written testimony of Michael Kades, Director of Markets and Competition Policy, Washington Center for Equitable Growth, at 15–16), https://docs.house.gov/meetings/JU/JU05/20190307/109024/HHRG-116-JU05-Wstate-KadesM-20190307-U1.pdf; *id.* (written testimony of Fiona Scott Morton, Professor of Economics, Yale School of Management, at 3), https://docs.house.gov/meetings/JU/JU05/20190307/109024/HHRG-116-JU05-Wstate-MortonF-20190307.pdf; *id.* (written testimony of Craig Garthwaite, Herman R. Smith Research Professor, Northwestern University Kellogg School of Management, at 7), https://docs.house.gov/meetings/JU/JU05/20190307/109024/HHRG-116-JU05-Wstate-GarthwaiteC-20190307.pdf.

[25] *Antitrust Concerns and the FDA Approval Process: Hearing Before the Subcomm. on Regulatory Reform, Commercial, and Antitrust Law of the H. Comm. on the Judiciary,* 115th Cong. (2017), https://docs.house.gov/meetings/JU/JU05/20170727/106333/HHRG-115-JU05-Transcript-20170727.pdf.

[26] *See generally id.* at 11 (testimony of Markus Meier, Acting Director, Bureau of Competition, Federal Trade Commission); *id.* at 31–32 (testimony of Alden Abbott, Deputy Director and Senior Legal Fellow, The Heritage Foundation); *id.* at 33–34 (testimony of Aaron S. Kesselheim, Associate Professor of Medicine, Harvard Medical School).

Committee Oversight Findings

In compliance with clause 3(c)(1) of rule XIII of the Rules of the House of Representatives, the Committee advises that the findings and recommendations of the Committee, based on oversight activities under clause 2(b)(1) of rule X of the Rules of the House of Representatives, are incorporated in the descriptive portions of this report.

New Budget Authority and Tax Expenditures

Clause 3(c)(2) of rule XIII of the Rules of the House of Representatives is inapplicable because this legislation does not provide new budgetary authority or increased tax expenditures.

Congressional Budget Office Cost Estimate

In compliance with clause 3(c)(3) of rule XIII of the Rules of the House of Representatives, the Committee sets forth, with respect to the bill, H.R. 2374, the following estimate and comparison prepared by the Director of the Congressional Budget Office under section 402 of the Congressional Budget Act of 1974:

H.R. 2374, Stop STALLING Act
As ordered reported by the House Committee on the Judiciary on April 30, 2019

By Fiscal Year, Millions of Dollars	2019	2019-2024	2019-2029
Direct Spending (Outlays)	0	-42	-98
Revenues	0	8	18
Deficit Effect	0	-50	-117
Spending Subject to Appropriation (Outlays)	0	-7	n.e.

Pay-as-you-go procedures apply?	Yes	Mandate Effects	
Increases on-budget deficits in any of the four consecutive 10-year periods beginning in 2030?	No	Contains intergovernmental mandate?	No
		Contains private-sector mandate?	No

n.e. = not estimated.

H.R. 2374 would authorize the Federal Trade Commission (FTC) to initiate a civil action against any persons involved with submitting certain petitions to the Food and Drug Administration (FDA) that are objectively without merit and who use the agency's administrative review process for the purpose of interfering with the business of a competitor. Such persons would be liable for violating the FTC Act. (Under the bill, the term "persons" includes individuals or entities.)

Under current law, section 505(q) of the Federal Food, Drug, and Cosmetic Act governs how certain petitions submitted to FDA are treated. Such petitions request FDA to take or refrain from taking an action by the agency that could delay approval of pending marketing applications, including applications for lower priced generic and biosimilar drugs. FDA's draft guidance details how FDA assesses whether a petition is submitted with the primary purpose of delaying the approval of an application. If such a determination is made, FDA may summarily deny the petition if it also does not on

its face raise valid scientific or regulatory issues. FDA may refer such cases to the FTC, although a recent appellate court ruling limits FTC's litigation authority in this area.

In addition to establishing a statutory framework for FTC's litigation authority, the bill also would allow FTC to impose civil penalties and seek other appropriate relief in district court from parties that violate antitrust law in this area. If FDA determines that a petition was submitted primarily to delay approval of a marketing application and refers it to the FTC, the bill would make such petitions presumptively illegal under the FTC Act, unless the defendant proves by preponderance of the evidence that the petition is not a sham.

Enacting H.R. 2374 would make it easier for the FTC to bring cases alleging that certain petitions are unlawful and to impose penalties. CBO expects the threat of substantial penalties would deter some parties from submitting petitions to FDA that would otherwise delay marketing of lower priced drugs.

To estimate the effects of reducing the number of sham petitions, CBO examined information about past cases involving petitions that potentially delayed the marketing approval for a competitor's drug. CBO estimates that the bill would affect between $1 billion and $2 billion of brand-name sales for drugs over the 2019–2029 period and would accelerate initial competition from generic or biosimilar products for affected drugs by six months, on average. Because CBO expects the bill would accelerate the availability of lower-priced drugs that would otherwise have been delayed, enacting H.R. 2374 would reduce the average price of drugs paid by federal health programs that purchase drugs or provide health insurance that covers drugs. As result, CBO estimates that the legislation would reduce mandatory spending by $98 million over the 2019–2029 period. By lowering the average cost for prescription drugs, we also estimate that premiums for some private health insurance plans would decrease under the bill. Lower premiums would reduce federal subsidies for insurance purchased through the marketplaces and shift compensation from tax-favored health insurance to taxable wages. Taken together, such changes would increase federal revenues by $18 million over the 2019–2029 period. In total, CBO estimates that enacting H.R. 2374 would decrease the deficit by $117 million over the 2019–2029 period.

CBO also estimates that implementing H.R. 2374 would decrease spending subject to appropriation by $7 million over the 2019–2024 period, assuming appropriation actions consistent with the bill. That decrease would result primarily because lower estimated drug prices would reduce costs for discretionary health programs.

The uncertainty in this estimate is driven primarily by the difficulty in predicting the number of frivolous petitions that are likely to be submitted to FDA through 2029 under current law and under the bill and estimating the amount of brand-name sales for drugs facing competition affected by such petitions. If fewer sham petitions were submitted to the FDA under the bill, its enactment could lead to earlier market entry by lower-priced drugs when both approval of the generic or biosimilar application and marketing of the drug hinge on the date that a petition is adjudicated by FDA. If patent-related issues would delay entry of generic or biosimilar drugs regardless of the date on which a petition is resolved, such

cases would not be affected by the bill. The timing and results of those legal proceedings are inherently uncertain. Such effects could differ from those included in CBO's analyses, depending on pharmaceutical companies' decisionmaking and the outcome of court proceedings.

Details of the estimated budgetary effect of H.R 2374 are shown in Table 1. Those effects fall primarily within budget functions 370 (commerce and housing credit), 550 (health), and 570 (Medicare).

TABLE 1.—ESTIMATED BUDGETARY EFFECTS OF H.R. 2374

	By fiscal year, millions of dollars—												
	2019	2020	2021	2022	2023	2024	2025	2026	2027	2028	2029	2019–2024	2019–2029
Decreases in Direct Spending													
Estimated Outlays [a]	0	−5	−9	−10	−9	−9	−10	−11	−11	−13	−12	−42	−98
On-Budget	0	−5	−9	−10	−9	−9	−10	−11	−11	−13	−12	−42	−98
Off-Budget [b]	0	*	*	*	*	*	*	*	*	*	*	*	*
Increases in Revenues													
Estimated Revenues ...	0	1	2	2	2	2	2	2	2	2	2	8	18
On-Budget	0	1	1	1	1	1	1	1	2	2	2	6	13
Off-Budget	0	*	*	*	*	*	*	1	1	1	1	2	5
Net Decrease in the Deficit From Changes in Direct Spending and Revenues													
Effect on the Deficit ...	0	−6	−11	−11	−11	−10	−12	−13	−13	−15	−14	−50	−117
On-Budget	0	−6	−11	−11	−10	−10	−11	−12	−13	−14	−14	−48	−111
Off-Budget	0	*	−1	−1	−1	−1	−1	−1	−1	−1	−1	−2	−5
Increases or Decreases (−) in Spending Subject to Appropriation													
Estimated Authorization	0	−1	−1	−1	−1	−1	n.e.	n.e.	n.e.	n.e.	n.e.	−7	n.e.
Estimated Outlays	0	−1	−1	−1	−1	−1	n.e.	n.e.	n.e.	n.e.	n.e.	−7	n.e.

Components may not sum to totals because of rounding; n.e. = not estimated; * = between −$500,000 and $500,000.
[a] Budget authority equals outlays.
[b] Includes off-budget effects on the operating costs of the U.S. Postal Service.

The CBO staff contact for this estimate is Julia Christensen. The estimate was reviewed by Leo Lex, Deputy Assistant Director for Budget Analysis.

Duplication of Federal Programs

No provision of H.R. 2374 establishes or reauthorizes a program of the Federal government known to be duplicative of another federal program, a program that was included in any report from the Government Accountability Office to Congress pursuant to section 21 of Public Law 111–139, or a program related to a program identified in the most recent Catalog of Federal Domestic Assistance.

Performance Goals and Objectives

The Committee states that pursuant to clause 3(c)(4) of rule XIII of the Rules of the House of Representatives, H.R. 2374 would lower drug prices by ending abuse of the citizen petition process by prescription drug companies or third parties acting on their behalf. The Stop STALLING Act would establish that using sham petitions to block generic competition is illegal under the FTC Act and establish a presumption of illegality when certain criteria are met—one of which is an HHS determination that the petition was submitted with the primary purpose of delaying approval of a new drug. The bill aims to strengthen the ability of the FTC to challenge citizen

petition abuse in court. The legislation also seeks to strengthen the FDA's ability to safely approve new drug applications by eliminating the diversion and waste of FDA resources spent on responding to sham petitions.

Advisory on Earmarks

In accordance with clause 9 of rule XXI of the Rules of the House of Representatives, H.R. 2374 does not contain any congressional earmarks, limited tax benefits, or limited tariff benefits as defined in clause 9(d), 9(e), or 9(f) of rule XXI.

Section-by-Section Analysis

The following discussion describes the bill as reported by the Committee.

Section 1. Short Title. Section 1 sets forth the short title of the bill as the "Stop Significant and Time-wasting Abuse Limiting Legitimate Innovation of New Generics Act" or the "Stop STALLING Act."

Section 2. Federal Trade Commission Enforcement Against Sham Petitions. Section 2 establishes that the submission of a covered petition or a series of covered petitions that is a sham is an unfair method of competition under section 5(a)(1) of the FTC Act (15 U.S.C. 45(a)(1)) and sets forth the circumstances when a covered petition is presumed to be part of a series of covered petitions that is a sham.

Subsection 2(a) sets forth various definitions.

Subsection 2(b)(1) provides that a person submitting or causing the submission of a covered petition or a series of covered petitions that is a sham shall be liable for engaging in an unfair method of competition under section 5(a)(1) of the FTC Act.

Subsection 2(c)(1) authorizes the FTC to initiate a civil action to recover a civil penalty and seek other appropriate relief in a U.S. district court if the FTC has reason to believe the submission of a covered petition or a series of covered petitions violates section 5(a)(1) of the FTC Act.

Subsection 2(c)(2) provides that, in a civil action under subsection 2(c)(1), a petition shall be presumed to be part of a series of covered petitions that is a sham if the Secretary of Health and Human Services has determined that the covered petition was submitted with the primary purpose of delaying the approval of a covered application, was part of a series of covered petitions, and has referred such determination to the FTC in writing with a reasoned basis for the determination.

Subsection 2(c)(3) provides that the presumption under subsection 2(c)(2) shall not apply if the defendant establishes by a preponderance of the evidence that the series of covered petitions that includes the covered petition referred by the Secretary of Health and Human Services to the FTC is not a sham.

Section 2(c)(4) provides for penalties. A civil penalty shall not be greater than the greater of: (A) any revenue earned from the sale of any drug referenced in a covered application that was the subject of a covered petition or a series of covered petitions that is a sham while the petition or petitions were under HHS review; or (B) $50,000 for each calendar day that each covered petition that is a

sham or that was part of a series of covered petitions that is a sham was under HHS review.

Section 2(c)(5) provides that nothing in this Act shall modify, impair, limit, or supersede the applicability of the antitrust laws.

Subsection 2(c)(6) provides that the civil penalty is in addition to, not in lieu of, any other remedies provided by federal law and that nothing in this subsection shall be construed to affect the FTC's authority under any other law.

Section 2(d) sets the Act's effective date, providing that it applies to all citizen petitions submitted on or after the date of enactment of the Act.

Section 3. Severability. Section 3 provides that if a provision of the Act is held unconstitutional the remainder of the Act will not be affected.

○