AMERICAN
ECONOMIC
LIBERTIES
PROJECT

May 17, 2021

The Honorable Carolyn B. Maloney, Chair
The Honorable James Comer, Ranking Member
House Committee on Oversight and Reform
2157 Rayburn House Office Building
Washington, D.C. 20515

Dear Chairwoman Maloney and Ranking Member Comer,

We are writing in regards to the Committee's May 18th Hearing that will include the testimony of AbbVie CEO Richard A. Gonzalez.

AbbVie along with its predecessor corporations Abbott, Forest Labs, Warner Chilcott, Allergan, and Actavis (collectively "AbbVie") have consistently and flagrantly violated Sections 1 & 2 of the Sherman Act by illegally extending patent monopolies.

While AbbVie may be most well-known for its ongoing conduct regarding Humira, the company has a long and well-documented history of illegally denying Americans access to low-cost generic drugs. AbbVie and its predecessors' entire business model in recent years has been to acquire older brand drugs that were about to face generic competition and then to illegally extend its monopoly on those drugs by using well-documented anticompetitive strategies including 'pay-for-delay,' market allocation, 'product hopping,' filing sham citizens petitions, fraud on the patent office, and filing sham patent litigation.

We have created the attached Table to show how AbbVie and its predecessors' have been accused of illegally extending monopolies regarding at least eleven (11) major brand drugs in the last ten years, including several blockbusters such as Namenda, Humira, Restasis, Bystolic, and AndroGel.[1]

Some information on the Table appears particularly relevant:

First, we estimate that AbbVie's illegal schemes on just these eleven drugs have caused Medicare Part D to spend ***an additional $20 billion on AbbVie's brand drugs instead of generic***

[1] The Table does not include antitrust lawsuits against AbbVie before the last ten years, the ongoing massive generic price-fixing litigation that includes claims against AbbVie entities, and the National Opioid Litigation. *See In re Abbott Norvir Antitrust Litigation*, 562 F. Supp. 2d 1080 (N.D. Cal. 2008); *In re Tricor Antitrust Litigation*, 05-340 (D. Del.) (product hopping) ($250 million settlement); *In re Doryx Antitrust Litigation* (Mylan v. Warner Chilcott), 12-3824 (E.D. Penn.) (product hopping); *In re Generic Pharmaceuticals Pricing Antitrust Litigation*, 16-md-2724 (E.D. Penn.); *In re National Prescription Opiate Litigation*, MDL No. 2804 (N.D. Ohio).

equivalents from 2012-19.[2] This is roughly half of all Medicare Part D spending on these eleven drugs from 2012-19.[3]

Second, this Table establishes that the Department of Justice Antitrust Division and the Federal Trade Commission have failed to enjoin, cease, or recover sufficient damages to disincentivize AbbVie from engaging in illegal conduct. This is particularly surprising in light of the fact that many of these cases, including *In re Namenda Antitrust Litigation*, *In re Restasis Antitrust Litigation*, and *In re Asacol Antitrust Litigation*, have already been extensively litigated and it would be relatively easy for the government to file follow-on cases.

Third, this Table establishes that private class actions, as they currently exist, do not sufficiently punish companies like AbbVie enough to deter continued illegal conduct. As shown, private claims are often spread among direct purchaser class actions, indirect purchasers class actions, and direct claims brought by major retailers. Unfortunately, private claimants often face enormous procedural barriers, especially at the class certification stage of litigation, that greatly reduce the likelihood of a substantial recovery and therefore reduces the effectiveness of private antitrust claims to deter future anticompetitive conduct.

Sincerely,

American Economic Liberties Project

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[2] This estimate is based on simple assumptions that generic drugs cost approximately 80% less and biosimilars cost approximately 25% less than competing brand products. The Table is intended to estimate the scale of the problem, not provide a precise damage model of every drug product. *See*, FDA, Generic Competition and Drug Prices (2019), *available at* https://www.fda.gov/about-fda/center-drug-evaluation-and-research-cder/generic-competition-and-drug-prices. This Table shows raw spending data and does not take into account the impact of Medicare Part D or Medicaid drug rebates.

[3] The spending data for Lo Loestrin Fe, a birth control drug, is taken from Medicaid instead of Medicare Part D.

Brand Name	FDA Approval	Litigation	Scheme Type(s)	Drug Co.
Namenda **Namenda XR** **Namzaric**	2003 2010 2014	In re Namenda Antitrust Litigation, 15-cv-07488 (S.D.N.Y.); Silbersher v. Allergan, 18-cv-03018 (N.D. Cal.)	Pay for Delay; Product Hopping; Sham Patent Listing; Fraud on the Patent Office	Forest/Allergan
Restasis **Restasis Multidose**	2002	In re Restasis Antitrust Litigatrion, 18-md-02819 (E.D.N.Y.)	Fraud on the Patent Office; Sham Patent Litigation; Sham Citizens Petitions	Allergan
Humira (All)	2002	In re Humira Antitrust Litigation, 19-cv-01873 (N.D. Ill.)	Sham Patent Thicketing; Pay-for-Delay (Mkt. Allocation)	AbbVie
Bystolic	2007	JM Smith Drug Corp. v. Abbvie, 20-cv-04581 (N.D. Cal.); Walgreen v. AbbVie, 20-cv-09793 (S.D.N.Y.);	Pay for Delay	Forest/Allergan
Androgel	2000	FTC v. AbbVie, 14-cv-05151 (E.D. Pa.); King Drug Co. v. Abbott Labs, 19-cv-03565 (E.D. Pa.)	Pay for Delay; Sham Patent Litigation	AbbVie
Lidoderm	1999	In re Lidoderm Antitrust Litigation, 14-md-02521 (N.D. Cal.); FTC v. Allergan, 17-cv-00312 (N.D. Cal.)	Pay for Delay (Generic Side); Sham Citizens Petitions (Against Endo)	Actavis/Allergan
Niaspan	1997	In re Niaspan Antitrust Litigation, 13-md-02460 (E.D. Penn.)	Pay for Delay	AbbVie
Asacol **Asacol HD** **Delzicol**	1992 2008 2013	In re Asacol Antitrust Litigation, 15-cv-12730 (D. Mass.)	Product Hopping; Pay for Delay	Warner Chilcott/Allergan

Lo Loestrin Fe	2010	In re Loestrin Antitrust Litigation, 13-md-02472 (D. R.I.)	Sham Patent Litigation; Pay for Delay; Product Hopping	Actavis/Allergan
Botox	1991	In Matter of Allergan and Inamed, FTC No. 061-0031 (2006); Tawfilis v. Allergan, 15-cv-00307 (S.D. Cal.);	Merger Violation; Pay for Delay (Mkt. Allocation)	Allergan
Zymar **Zymaxid**	2003 2010	Hartig Drug Co. v. Senju, 14-cv-00719 (D. Del.); Apotex v. Allergan, 12-cv-00196 (D. Del.)	Sham Patent Litiation; Fraud on the Patent Office; Product Hopping	Allergan

Total Spending (2012-19)	Est. Over-Spending	FTC or DOJ Enforcement?	But-For Generic Entry	Actual (Expected) Gx Entry	Litigation Outcome or Current Status
$9,454,044,086	**$7,563,235,269**	**No**	9/22/11	7/11/15	Direct Purchasers settled for $750 million. The Silbersher False Claims lawsuit is pending after beating Motion to Dismiss.
$6,997,357,026	**$4,470,497,129**	**No**	5/17/14	(No Gx to Date)	Direct Purchasers settled for $51.25 million. Indirect Purchaser class certified and pending.
$16,256,702,330	**$2,381,638,259**	**No**	12/31/16	(6/30/2023)	District Court dismissed plaintff's patent thicket and market allocation theories. Plaintiffs appealed and 7th Circuit decision pending.
$2,580,652,591	**$2,064,522,073**	**No**	12/17/11	(9/17/2021)	Several class and individual purchaser actions filed in 2020 and pending.
$1,744,393,042	**$1,268,555,349**	**Yes (But FTC recovery overturned.)**	6/1/12	10/15/18	In FTC action, District Court ruled AbbVie used sham litigation and awarded $448 million under 13(b). Third Circuit overturned FTC's 13(b) authority and reinstaed the pay-for-delay claim. The Direct Purchaser class action is pending.
$1,872,645,537	**$850,673,641**	**Yes (But no monetary recovery.)**	8/1/12	9/1/13	Direct Purchasers settled for $166 million. Indirect Purchasers settled for $104.75 million. FTC filed complaint regarding Lidoderm in 2016 and then settled that action without monetary recovery.
$836,259,407	**$643,332,604**	**No**	4/5/09	6/26/14	Direct Purchaser class certified and pending. Indirect Purchaser class denied class cert and pending. Individual retailer cases pending.
$825,779,393	**$545,171,760**	**No**	7/31/13	(Limited Gx to Date)	Direct Purchasers settled for $15 million. Indirect Purchasers class certified and then overturned on appeal by the First Circuit.

$278,477,038	**$222,781,630**	**No**	9/1/09	(No Gx to Date)	Indirect Purchasers settled claims for $62.5 million. Direct Purchasers settled claims for $120 million. Others claims from CVS and Rite Aid were settled for undisclosed amounts.
$232,369,321	**$48,666,756**	**No**	1/1/08	(Limited Gx to Date)	FTC required divestment of emerging Botox competitior as part of a 2005 merger. That competitor never came to market. Direct Purchasers settled Tawfillis case for $13.45 million.
$55,134,650	**$37,013,912**	**No**	6/15/10	2/3/13	Direct Purchasers settled for $9 million. Apotex reached undisclosed settlements in its competitor antitrust cases against Allergan, Kyorin, and Senju.
$41,133,814,422	**$20,096,088,381**				

But-For Market Assumptions
80% less spending 2012-19. Smaller share to next generation products.
80% less spending 2015-19. Smaller share to next generation product.
25% less spending 2017-19. Biosimlars are less affordable.
80% less spending 2012-19.
80% less spending 2013-19. Smaller share to next generation product.
80% less spending 2013-15.
80% less spending 2012-14.
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Bystolic	2007	JM Smith Drug Corp. v. Abbvie, 20-cv-04581 (N.D. Cal.); Walgreen v. AbbVie, 20-cv-09793 (S.D.N.Y.);	Pay for Delay
Androgel	2000	FTC v. AbbVie, 14-cv-05151 (E.D. Pa.); King Drug Co. v. Abbott Labs, 19-cv-03565 (E.D. Pa.)	Pay for Delay; Sham Patent Litigation
Lidoderm	1999	In re Lidoderm Antitrust Litigation, 14-md-02521 (N.D. Cal.); FTC v. Allergan, 17-cv-00312 (N.D. Cal.)	Pay for Delay; Sham Citizens Petitions (Against Endo)
Niaspan	1997	In re Niaspan Antitrust Litigation, 13-md-02460 (E.D. Penn.)	Pay for Delay
Asacol **Asacol HD** **Delzicol**	1992 2008 2013	In re Asacol Antitrust Litigation, 15-cv-12730 (D. Mass.)	Product Hopping; Pay for Delay

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Drug Co.	But-For Generic Entry	Actual (Expected) Generic Entry	Part D Spending (2012)	Part D Spending (2013)	Part D Spending (2014)	Part D Spending (2015)	Part D Spending (2016)
Forest/Allergan	9/22/11	7/11/15	$1,327,413,176	$1,611,131,908	$1,886,948,787	$1,634,745,630	$1,131,842,218
AbbVie	12/31/16	(6/30/2023)	$674,609,130	$955,331,811	$1,239,853,884	$1,662,281,578	$2,198,072,891
Allergan	5/17/14	(No Gx to Date)	$337,138,186	$470,905,008	$601,192,421	$774,629,534	$949,331,115
x f	12/17/11	(9/17/2021)	$160,940,071	$227,001,921	$270,603,203	$337,342,515	$347,839,941
AbbVie	6/1/12	10/15/18	$158,698,856	$264,323,212	$259,441,150	$244,703,398	$242,838,002
Actavis/Allergan	8/1/12	9/1/13	$ 638,803,344	$ 704,990,899	$ 358,351,152	$107,473,365	$22,518,185
AbbVie	4/5/09	6/26/14	$360,725,199	$377,119,776	$66,320,780	$7,810,269	$4,760,014
Warner Chilcott/Allergan	7/31/13	(Limited Gx to Date)	$28,570,033	$115,744,660	$154,674,621	$118,397,464	$132,301,100

Actavis/Allergan	9/1/09	(No Gx to Date)	$24,242,617	$30,122,676	$30,911,807	$31,827,828	$34,098,920
Allergan	1/1/08	(Limited Gx to Date)	$8,627,770	$12,620,223	$16,454,304	$20,727,033	$29,180,158
Allergan	6/15/10	2/3/13	$26,043,799	$20,223,591	$4,187,883	$1,764,737	$2,359,745

Part D Spending (2017)	Part D Spending (2018)	Part D Spending (2019)	Total Spending (2012-19)	Total Est. Damages	FTC or DOJ Enforcement?
$1,092,822,567	$507,452,829	$261,686,971	**$9,454,044,086**	**$7,563,235,269**	No
$2,638,613,641	$3,168,910,239	$3,719,029,156	**$16,256,702,330**	**$2,381,638,259**	No
$1,132,880,948	$1,300,546,991	$1,430,732,822	**$6,997,357,026**	**$4,470,497,129**	No
$376,218,897	$406,216,447	$454,489,596	**$2,580,652,591**	**$2,064,522,073**	No
$268,207,249	$258,946,027	$47,235,148	**$1,744,393,042**	**$1,268,555,349**	Yes (But FTC recovery overturned.)
$14,991,465	$12,935,938	$12,581,190	**$1,872,645,537**	**$850,673,641**	Yes (But no monetary recovery.)
$6,673,518	$7,886,257	$4,963,594	**$836,259,407**	**$643,332,604**	No
$114,538,061	$97,957,465	$63,595,989	**$825,779,393**	**$545,171,760**	No

$38,121,569	$42,481,712	$46,669,909	**$278,477,038**	**$222,781,630**	No
$39,077,698	$49,749,780	$55,932,354	**$232,369,321**	**$48,666,756**	No
$368,562	$101,817	$84,517	**$55,134,650**	**$37,013,912**	No
			$41,133,814,422	**$20,096,088,381**	

Litigation Outcome or Current Status	But-For Market Assumptions
Direct Purchasers settled for $750 million. The Silbersher False Claims lawsuit is pending after beating Motion to Dismiss.	80% less spending 2012-19. Smaller share to next generation products.
District Court dismissed plaintff's patent thicket and market allocation theories. Plaintiffs appealed and 7th Circuit decision pending.	50% less spending 2017-19. Biosimlars are less affordable.
Direct Purchasers settled for $51.25 million. Indirect Purchaser class certified and pending.	80% less spending 2015-19. Smaller share to next generation product.
Several class and individual purchaser actions filed in 2020 and pending.	80% less spending 2012-19.
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