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● Friends Fiduciary Corporation ● Illinois State Treasurer ● Miller/Howard Investments ●
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● Sisters of the Presentation of the Blessed Virgin Mary ● Trinity Health ●
UAW Retiree Medical Benefits Trust**

December 8, 2017

Submitted electronically via https://ftcpublic.commentworks.com/ftc/pharmaworkshop

Maureen K. Ohlhausen
Acting Chairwoman
Federal Trade Commission
407 7th St. S.W.
Washington, DC 20024

RE: Federal Trade Commission Workshop on "Understanding Competition in Prescription Drug Markets: Entry and Supply Chain Dynamics"

Dear Chairwoman Ohlhausen:

The undersigned institutional investors thank the Federal Trade Commission (FTC) for the opportunity to submit a comment on competition in the prescription drug markets. Specifically, we would like to address investor concerns about brand companies' use of the Risk Evaluation Management System (REMS) programs to block generic competition[1] and to seek FTC support for a proposal made by the Food and Drug Administration (FDA) Commissioner Scott Gottlieb at a recent FDA meeting to identify brand name companies that abuse the REMS programs.[2] In our view, this strategy combined with the strengthened enforcement provisions in the proposed bipartisan CREATES Act (S. 974 & H.R. 2212) would enable investors to hold brand companies accountable for REMS related anticompetitive activities that thwart market competition, innovation, and patient access to affordable and quality medicines. Currently, investors have little to no information about which companies may be abusing the REMS process and, frequently, when legal actions are taken, too much time has elapsed, and investors have difficulty in holding corporate board directors accountable for related legal, reputational, and financial risks.

Among anticompetitive practices, REMS abuse has the potential to impose significant business risk for investors given the number of drugs expected to be approved with elements to assure safe use (ETASU), representing now 60% of all REMS programs. Companies may use the REMS ETASU program to deny generic drug manufacturers access to the necessary number of doses needed to complete bioequivalence testing for FDA approval. Studies have shown that without a meaningful number of generics on the market (three or more) competition that results in lower prices is difficult to achieve. While safety

[1] REMS is a Risk Evaluation and Mitigation Strategy, a plan that uses "risk minimization strategies beyond the professional labeling to ensure that the benefits of certain prescription drugs outweigh their risks." (https://www.fda.gov/downloads/aboutfda/transparency/basics/ucm328784.pdf).
[2] Gottlieb, Scott, "Opening Remarks for Part 15 Public Meeting on Generic Drug Companies," July 18, 2017.

measurers embedded in the REMS programs are critical to patient health, an abuse of the regulatory system unrelated to safety issues perpetuates market dysfunction and thwarts innovation.

In addition, there also is an increasing use of restricted distribution channels to delay or block generics developers even without an FDA required REMS ETASU program in place.[3] As mentioned above, investors are not only concerned about mitigating business risks but also about how REMS abuse may hinder investments in profitable generic and biosimilar markets.

Institutional investors are providers of capital to companies regulated by both the FTC and the FDA and as such have a strong interest in supporting measures to promote a sustainable and profitable healthcare market. As long-term investors, we have broad equity exposure across the healthcare market, including investments in brand, generic, and biosimilar companies and, as such, rely on competition and innovation as key drivers of long-term shareholder value. Anticompetitive practices involving REMS, Orphan Drug Designation, Pay for Delay arrangements, product-hopping, and the Citizen Petition Process pose business risks and may curb investors' opportunities to invest in profitable markets such as biosimilars which are expected to grow to $11 billion in value in 2020.[4]

Investors rely on the boards of directors of pharmaceutical companies to exercise risk oversight in key decisions that affect shareholder value, including complying with regulations and pursuing business strategies that are long-term growth oriented and not short-term profit motivated. This long-term horizon is aligned with the interests of institutional investors which typically have pension and health care financial obligations for decades to come. The board's risk oversight is expected to mitigate not only financial risks, but operational, reputational, and legal risks as well. With practices such as inappropriate use of REMS, the pharmaceutical company is exposed to a number of these kinds of risks.

Through our equity ownership, investors engage with the boards of directors to ensure that they are equipped with the knowledge and capacity to effectively exercise their oversight duty, including anticipating a regulatory environment in which the use of REMS is scrutinized for abuse, bringing with it legal and reputational risks. If the CREATES Act becomes law and the FDA discloses the identity of companies that have engaged in inappropriate use of REMS, investors will need that information to be positioned to engage with boards of directors of FDA identified companies to ensure that appropriate risk oversight and compliance measures are in place. Through the exercise of shareholder rights, investors are able to vote for directors that pledge to upheld the highest standards of ethical conduct and pursue business strategies that promote competition and innovation.

While the CREATES Act would introduce new litigative options, even in the current legal environment, companies may be exposed to private lawsuits. One example is Mylan's antitrust lawsuit against Celgene for failure to provide product samples of thalamic and revlimid, now pending in the Federal District Court of New Jersey.

Investors would also be able to engage with corporate boards on actions that may raise reputational risks. REMS-related activities are susceptible to these risks as evidenced by the highly publicized example in 2015 when public scrutiny, including legislative hearings, put the spotlight on Turing Pharmaceutical's'

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[3] Brill, Alex, "REMS and Restricted Distribution Programs: An Estimate of the Market," June 2017 available at http://www.gphaonline.org/media/cms/Alex_Brill_REMS_Study_June_2017.pdf; also see Carrier, Michael A., "Biologics: The New Antitrust Frontier," Univ. of Ill. Law Review, at 49 (forthcoming 2018), available at https://papers.ssrn.com/sol3/papers.cfm?abstract_id=2982190.

[4] "Biosimilars Market Worth 10.90 Billion USD By 2021," Biosimilar Development, January 6, 2017 available at: https://www.biosimilardevelopment.com/doc/biosimilars-market-worth-billion-usd-by-0001.

practice of restricting the distribution of Daraprim to generic companies seeking to use product samples to manufacture less expensive alternatives.

Currently, investors have little information about which companies are subverting the intent of the Hatch-Waxman Amendments by using the REMS program to block the entry of generics and biosimilars into the market. When allegations become public, it is generally years after the time period in which these harmful practices have occurred. This time lag significantly limits investors' ability to hold directors and executives accountable for lapses in governance and risk oversight.

The public information that does exist points to a disturbing trend in the growing number of REMS abuse allegations. FDA has received over 150 complaints from generic companies that have been unable to get product samples from brand companies to conduct bioequivalence testing necessary for FDA approval.[5]

One example of a company that used a suite of anticompetitive practices, including REMS, is Reckitt Benckiser, the company that spun off Indivior, a manufacturer of the drug Suboxone, used to treat opioid addiction. Forty-one states have sued Reckitt and Indivior, alleging that Reckitt introduced Suboxone sublingual film in 2007, and moved patients from the tablet to the film, in order to ensure that pharmacists would not be able to substitute generic buprenorphine/naloxone tablets (which would not have been therapeutically equivalent) for the branded Suboxone product, once the FDA approved those generic versions. As well, the states' lawsuit claims that Reckitt raised baseless safety concerns about the safety of buprenorphine/naloxone tablets before pulling them from the market, refused to cooperate with an FDA-ordered shared REMS with other buprenorphine manufacturers, and filed an unsupported citizen's petition asking the FDA to delay approving generic buprenorphine/naloxone tablets. Generic buprenorphine/naloxone tablets did not make it to market until 2013.[6]

In addition to these suits by the states' Attorneys Generals' offices, the FTC has also launched an investigation into whether Reckitt engaged in unfair competition with respect to Suboxone. The FTC's Civil Investigative Demand cites some of the same conduct alleged in the states' complaint.[7] These tactics have been characterized in the press as a "shocking scheme"[8] and "profiteering."[9] As investors, we are concerned that Indivior has suffered, and will continue to suffer, reputational damage and financial liability as a result of these efforts it and Reckitt made to delay and prevent generic competition and prop up prices for patients and payers. Investors are currently engaging with Indivior over these business risks described above, calling on the board of directors to implement certain corporate governance reforms that

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[5] Woodcock, Janet, Director, Center for Drug evaluation, Testimony on Generic Drug User Fee Act Reauthorization (GDUFA II), Biosimilar User Fee Act Reauthorization (BsUFA II) before the U.S. House of Representatives, Committee on Energy and commerce Subcommittee on Health, March 2, 2017 .

[6] The Complaint in the states' lawsuit can be found at https://www.doj.state.wi.us/sites/default/files/newsmedia/Suboxone_RedactedComplaint.pdf.

[7] See https://www.leagle.com/decision/infdco20150316867 (ruling on privilege).

[8] Christopher Moraff, "Suboxone Creator's Shocking Scheme to Profit Off of Heroin Addicts," *The Daily Beast*, Oct. 5, 2016 (available at https://www.thedailybeast.com/suboxone-creators-shocking-scheme-to-profit-off-of-heroinaddicts).

[9] Chris McGreal, "Reckitt Benckiser Sued by 35 US States For 'Profiteering' From Opioid Treatment," *The Guardian*, Oct. 21, 2016 (available at https://www.theguardian.com/business/2016/oct/21/reckitt-benckiser-drugcompany-sued-suboxone-profiteering-opiod-addiction).

would strengthen board oversight over these practices.[10] Disclosure of whether Indivior is one of the companies in receipt of an FDA REMS related letter would benefit investors in this engagement related to board accountability.

As the Reckitt/Indivior example shows, investors would benefit from timely, transparent information afforded by the FDA's disclosure of the REMS letters to branded companies. Institutional investors would be significant users of the FDA REMS letters as they seek to oversee the governance of their invested dollars. Without the FDA REMS letters, institutional investors remain in the dark about these important lapses in legal and reputational risk mitigation by pharmaceutical companies. We urge the FTC to support this strategy and would be happy to provide any additional information to the FTC on our views, and we look forward to working with you on our shared goals of ensuring competition and innovations in our capital markets alongside safe, affordable, and accessible healthcare.

Should you have any questions, please contact Meredith Miller, Chief Corporate Governance Officer for the UAW Retiree Medical Benefits Trust at mamiller@rhac.com or (734-929-5789).

Sincerely,

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[10] *$1.3 Trillion Investor Coalition on Opioid Accountability Launched*, available at http://uawtrust.org/AdminCenter/Library.Files/Media/501/About%20Us/$1.3-Trillion-Investor-Coalition-on-Opioid-Accountability-Launched.pdf.

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