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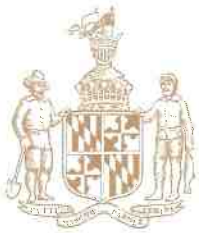

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CONFIDENTIAL
January 4, 2019

The Honorable Joseline A. Peña-Melnyk
P.O. Box 1251
College Park, Maryland 20741

Dear Delegate Peña-Melnyk:

You have asked for advice concerning proposed legislation creating a Prescription Drug Affordability Board. Specifically, you have asked about the legality of the proposed legislation. It is my view that the proposed legislation does not violate the Commerce Clause of the United States Constitution. It is also my view, however, that there is some risk that the proposed legislation could be found to be preempted by reason of conflict with United States Patent law. Moreover, to the extent the proposed legislation would regulate the prices that self-insured plans pay for prescription medications, it could be preempted by the Employee Retirement Income Security Act ("ERISA").

The proposed legislation would create a five member Prescription Drug Affordability Board ("the Board") for the purpose of protecting State residents, State and local governments, commercial health plans, health care providers, pharmacies, and other stakeholders within the health care system from high costs of prescription drugs. It would also create a twenty one member Prescription Drug Affordability Stakeholder Council ("the Council") to provide input to the Board on its decisions. The Board would be required to meet in open session at least every six weeks to review prescription drug product information. It may, however meet in closed session to discuss proprietary data and information so long as decisions are made in open session. The Board is to be funded by an assessment on all manufacturers that 1) engaged in the manufacture of a prescription drug or biologic for which it owns the FDA approved license; or 2) leases the market rights for an FDA licensed prescription drug or biologic from another; and 3) sets or changes the wholesale drug or biologic it manufactures or markets.[1]

The proposed legislation requires the Board to identify brand-name drugs and biologics, including biosimilars, licensed under a new drug application or biologics license application that have a launch price of $30,000 or more for a year or course of treatment, or a price increase of $3,000 or more in any other twelve-month period, or course of treatment if less than twelve

[1] The tabulation used is not clear, but I assume that a person is a manufacturer if it meets 3) and either 1) or 2).

months. The Board is also to identify generic drugs licensed under an abbreviated new drug application with a price increase of $300 or more in any twelve-month period, or course of treatment if less than twelve months. In addition, the Board may, in consultation with the Council, identify additional prescription drug costs that may create affordability challenges for the State health care system, including patients.[2] Pricing information is to be obtained by entering into memoranda of understanding to which manufacturers already report drug pricing information and accessing other available drug pricing information. Where there is no publicly available source for pricing information, the board is to request information from manufacturers of identified drugs with respect to pricing rationales. The information requested is to include documents and research related to the manufacturer's selection of the introductory price or price increase, including life-cycle management, net average price in the State, market competition and context, projected revenue, and the estimated value or cost-effectiveness of the product, if available.

Once prescription drug products are identified as required, the Board is to consult with the Council about the identified drugs and review the drug pricing to determine whether "utilization of the drug that is fully consistent with the federal Food and Drug Administration ("FDA") label has led or will lead to affordability challenges for the state health care system, including patients." Section 21-2C-07(d). The factors that may be considered by the Board in making this determination include 1) the wholesale acquisition cost in the State; 2) the average monetary price concession, discount, or rebate the manufacturer provides or is expected to provide to health plans in the State for that drug and for therapeutic alternatives; 3) the total amount of the price concession, discount, or rebate the manufacturer provides to pharmacy benefit managers in the State for that drug and for therapeutic alternatives; 4) the price at which therapeutic alternatives have been sold in the State; 5) the impact on patient access resulting from the cost of the product relative to insurance benefit design; 6) the current or expected dollar value of drug-specific patient access programs that are supported by the manufacturer; 7) the relative financial impacts to health, medical, or social services costs as can be quantified ad compared to baseline effects of existing therapeutic alternatives; 8) and any other factor established in Board regulations.

If consideration of these factors does not permit the Board to conclude whether a prescription drug product will produce or has produced challenges to the affordability of the drug for the state health care system, the Board may also consider manufacturer research and development costs, direct-to-consumer marketing costs, gross and net manufacturer revenues, any additional factors proposed by the manufacturer that the Board considers relevant, and any additional factors established by the Board by regulation.

If the Board determines that spending on a prescription drug product does create affordability challenges for the state health care system, it is required to establish an upper payment

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[2] These provisions do not apply to a drug used in an inpatient setting if the drug is regulated by the Health Services Cost Review Commission. In addition, they are not to be construed to prevent a manufacturer from marketing a product approved by the FDA while the product is under review by the Board. Furthermore, nothing in the subtitle may be construed to affect the eligibility of an entity for the 340B prescription drug discount program or the discounts that are available to an entity that is eligible for that program.

limit that applies to all purchases and payor reimbursements of the prescription drug product in the State.

A decision of the Board can be appealed to the Board itself and an adverse decision of the Board on this appeal is subject to judicial review under the Administrative Procedures Act. The provisions of the proposed legislation would be enforced by the Office of the Attorney General, which may pursue any available remedy under State law.

COMMERCE CLAUSE

The Commerce Clause of the United States Constitution provides that Congress shall have Power "[t]o regulate Commerce with foreign Nations, and among the several States." U. S. Const., Art. I, § 8, cl. 3. Although the Clause is a grant of power to Congress, it has long been recognized to have a "negative" or "dormant" aspect that "prohibits States from 'advanc[ing] their own commercial interests by curtailing the movement of articles of commerce, either into or out of the state.'" *Fort Gratiot Sanitary Landfill, Inc. v. Michigan Dept. of Natural Resources*, 504 U. S. 353, 359 (1992).

The determination of whether a state statute violates the dormant Commerce Clause involves a two-tier analysis. *Brown v. Forman Distillers Corp. v. New York State Liquor Authority*, 476 U.S. 573, 579 (1986). First, "[w]hen a state statute directly regulates or discriminates against interstate commerce, or when its effect is to favor in-state economic interests over out-of-state interests," the statute is virtually *per se* unconstitutional. *Philadelphia v. New Jersey*, 437 U.S. 617, 624 (1978). Such a statute will be upheld only if the discrimination is demonstrably justified by a valid factor unrelated to economic protectionism. *Id.* A statute that does not discriminate against interstate commerce, but regulates evenhandedly to effectuate a legitimate local public interest, and its effects on interstate commerce are only incidental, it will be upheld unless the burden imposed on such commerce is clearly excessive in relation to the putative local benefits. *Pike v. Bruce Church, Inc.*, 397 U. S. 137, 142 (1970).

The proposed legislation cannot be said to discriminate against interstate commerce. Its focus is solely on the price of prescription drug products in Maryland and the effects of such prices on the state health care system. The upper payment limit applies only to purchases and payor reimbursements in the State. Moreover, the factors to be considered in determining whether prices are excessive are based on prices, price concessions, discounts, and rebates available in this State and effects of those prices, price concessions, discounts, and rebates on access to health care in this State. To the extent that the proposed legislation placed requirements on manufacturers at all, they apply equally to all manufacturers who manufacture prescription drug products that are sold in the State, whether the manufacturer is located in the State or outside the State. Thus, the proposed legislation does not directly regulate or discriminate against interstate commerce.

It has also been held, however, that a law may be found to "directly regulate" interstate commerce if it has extraterritorial effect, that is, when it regulates transactions between manufacturers and wholesalers that take place wholly outside the state. *Healy v. Beer Inst., Inc.*, 491 U.S. 324, 337-340 (1989)); *Baldwin v. G.A.F. Seelig, Inc.*, 294 U.S. 511, 524 (1935); *Brown-*

Forman v. New York State Liquor Authority, 476 U.S. 573, 582-583 (1986). In *Pharm. Research & Mfrs. of Am. v. District of Columbia*, 406 F. Supp. 2d 56 (D.D.C. 2005), the court applied the extraterritoriality principal to a District of Columbia law that made it unlawful for any drug manufacturer or licensee thereof "to sell or supply for sale or impose minimum resale requirements for a patented prescription drug that results in the prescription drug being sold in the District for an excessive price." The court held that this law regulated transactions between manufacturers and wholesalers, by basing permissible prices on the prices charged in other states and would affect transactions taking place wholly outside the District of Columbia and was, for that reason, invalid. *Id.* at 68-70.

As I pointed out in my letter of January 31, 2018, the extraterritoriality principle is generally understood to apply only to price control and price affirmation statutes. *Ass'n des Eleveurs de Canards et d'Oies du Quebec v. Harris*, 729 F.3d 937, 951 (9th Cir. 2013); *IMS Health Inc. v. Mills*, 616 F.3d 7, 30 (1st Cir. 2010), *vacated sub nom. on other grounds IMS Health, Inc. v. Schneider*, 564 U.S. 1051 (2011). In *Association for Accessible Meds. v. Frosh*, 887 F.3d 664 (4th Cir. 2018), the Fourth Circuit applied the extraterritoriality concept more broadly to find that Maryland's price gouging act, which prohibited "price gouging in the sale of an essential off-patent or generic drug," that "is made available for sale in [Maryland]," Health - General Article ("HG"), § 2-802(a), "allow[ed] Maryland to enforce the [price gouging statute] against parties to transactions that did not result in a single pill being shipped to Maryland." *Accessible Medicine* at 671. As a result, the court found that the price gouging statute had invalid extraterritorial effect and thus violated the Commerce Clause. *Id.* at 672. This interpretation also relied on a broad reading of the statute that was not put forward by the State. As a result, the Office of the Attorney General filed a petition for certiorari in the case on October 19, 2018. After the Association for Accessible Medicine filed a waiver stating that they did not intend to file a response unless one was requested by the Court, the Supreme Court requested that a response to the writ of certiorari be file. The time to respond has been extended to January 14, 2019.

Even if the decision in *Accessible Medicine* is ultimately found to be correct, however, the approach taken by the proposed legislation does not lend itself to the broad interpretation applied to the price gouging law. As discussed above, the upper payment limits apply only to purchasers and payors in the State. While the proposed legislation has price control elements, it would not limit prices charged by manufacturers or wholesalers, but instead limits what payors and consumers in the State can pay, with the result that there would be no effect on transactions taking place entirely outside of the State. While out-of-state entities may have to choose between accepting payment at the levels set or withdrawing the drug in question from sale in the State, the Supreme Court has expressly recognized that for purposes of dormant Commerce Clause analysis, a state statute does not have an impermissible extraterritorial impact simply because it may require out-of-state companies to modify their distribution systems as a condition of continuing to sell their products in the regulating state. *See Exxon Corp. v. Governor of Maryland*, 437 U.S. 117, 127 (1978) ("We cannot . . . accept appellants' underlying notion that the Commerce Clause protects the particular structure or methods of operation in a retail market. . . . [T]he Clause protects the interstate market, not particular interstate firms, from prohibitive or burdensome regulations."). Thus, it is my view that the proposed legislation does not directly regulate or discriminate against interstate commerce.

It is difficult to predict what incidental burdens price controls might place on interstate commerce. If the response is that a prescription medication becomes unavailable in the State, the effect would probably be to drive some consumers to neighboring states and thus benefit pharmacies in those states, while possibly lowering overall sales by the manufacturer somewhat. If sales in the State are continued, sales may increase at the lower price, or the manufacturer or wholesaler may raise the price elsewhere to make up any loss. Any such effect must be balanced against the legitimate local interests that are served. In this instance, there can be no doubt that prescription drug prices are a major element in the overall cost of health care and that exorbitant prices can prevent some citizens from getting the health care they need. As a result, a serious burden would be necessary in order to establish a violation of the dormant Commerce Clause. Certainly, it cannot be said that the proposed legislation, on its face, would support a finding of such a burden.

For the above reasons it is my view that the proposed legislation would likely be upheld against a Commerce Clause Challenge.

SUPREMACY CLAUSE - PATENT LAW

The Supremacy Clause of the United States Constitution states that "the Laws of the United States ... shall be the supreme Law of the Land." U.S. Const. art. VI, § 1, cl. 2. Under this provision, State law may be preempted by federal law. *Sears, Roebuck & Co. v. Stiffel Co.*, 376 U.S. 225, 229 (1964) ("When state law touches upon the area of these federal statutes, it is 'familiar doctrine' that the federal policy 'may not be set at naught, or its benefits denied' by the state law."). This preemption may be in the form of express preemption, where a federal law expressly preempts state law, field preemption, where Congress has so clearly occupied the field as to express the intent to exclude state regulation; and conflict preemption, which arises where "compliance with both federal and state regulations is a physical impossibility" or where a "state law 'stands as an obstacle to the accomplishment and execution'" of the federal scheme. *Id.*

There is a question whether the proposed legislation would be preempted by federal patent law. The United States Constitution grants Congress the power to "promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries." U.S. Constitution, Article I, § 8, cl. 8. The resulting law provides that a person who "invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title." 35 U.S.C. § 101. The patent is typically valid for 20 years from the date on which the application was filed and grants:

> the right to exclude others from making, using, offering for sale, or selling the invention throughout the United States or importing the invention into the United States, and, if the invention is a process, of the right to exclude others from using, offering for sale or selling throughout the United States, or importing into the

> United States, products made by that process, referring to the specification for the particulars thereof.

35 U.S.C. § 154(a)(1) and (2).

With respect to pharmaceuticals, federal law permits extension of the patent term to compensate for delay caused by review by the federal Food and Drug Administration. 35 U.S.C. § 156(a). This extension was added by the Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. 98-417, commonly known as the Hatch-Waxman Act. In this Act Congress sought to "str[i]ke a balance between two competing policy interests: (1) inducing pioneering research and development of new drugs and (2) enabling competitors to bring low-cost, generic copies of those drugs to market." *Andrx Pharm., Inc. v. Biovail Corp.*, 276 F.3d 1368, 1371 (Fed. Cir. 2002).

There seems to be no dispute that the patent laws, including Hatch-Waxman, do not expressly preempt state legislation that touches upon patents. *Biotechnology Industry Org. v. District of Columbia*, 496 F.3d 1362, 1372 (Fed. Cir. 2007); *Biotechnology Industry Org. v. District of Columbia*, 505 F.3d 1343, 1348-1349 and n. 1 (Fed. Cir. 2007) (Dyk, J., dissenting); Serena Lipski, *Excessive Pricing and Pharmaceuticals: Why the Patent Act Does Not Preempt State Regulation of Pharmaceutical Prices*, 39 U. Tol. L. Rev. 913, 927 (2008); Christopher Lee Lockwood, *Biotechnology Industry Organization v. District of Columbia: A Preemptive Strike Against State Price Restrictions on Prescription Pharmaceuticals*, 19 Alb. L.J. Sci. & Tech. 143, 175-176 (2009).

Field preemption would be found only if congressional action has been so complete in the field of intellectual property law that there is no room for state regulation. Christopher T. Blackford, *Attention Shoppers: The Federal Circuit's Failure to Preempt Contractual Provisions Prohibiting Reverse Engineering May Create a Blue Light Special on Jurisdictional Forums*, 57 SMU L. REV. 63, 71 (2004). A finding of preemption on this basis would be inconsistent with Supreme Court cases indicating that the states are not foreclosed from regulating in the field of intellectual property. *See Kewanee Oil Co. v. Bicron Corp.*, 416 U.S. 470, 479 (1974) ("Just as the States may exercise regulatory power over writings, so may the States regulate with respect to discoveries. States may hold diverse viewpoints in protecting intellectual property relating to invention as they do in protecting the intellectual property relating to the subject matter of copyright. The only limitation on the States is that, in regulating the area of patents and copyrights, they do not conflict with the operation of the laws in this area passed by Congress."); *Aronson v. Quick Point Pencil Co.*, 440 U.S. 257, 262 (1979) ("State law is not displaced merely because the contract relates to intellectual property which may or may not be patentable; the states are free to regulate the use of such intellectual property in any manner not inconsistent with federal law."). *See also* Christopher Lee Lockwood, *Biotechnology Industry Organization v. District of Columbia: A Preemptive Strike Against State Price Restrictions on Prescription Pharmaceuticals*, 19 Alb. L.J. Sci. & Tech. 143, 178-179 (2009); *but see Biotechnology Industry Org. v. District of Columbia*, 505 F.3d 1343, 1349 (Fed. Cir. 2007) (Dyk, J., dissenting). In light of the foregoing

authority, field preemption would not be applicable. *Pharm. Research & Mfrs. of Am. v. District of Columbia*, 406 F.Supp.2d 56 (2005).[3]

With respect to conflict protection, it is clearly not impossible to comply with both the patent law and the proposed legislation. In *Pharm. Research & Mfrs. of Am. v. District of Columbia*, 406 F.Supp.2d 56 (D.D.C. 2005), however, the court held that a District of Columbia law making it unlawful for a drug manufacturer "to sell or supply for sale or impose minimum resale requirements for a patented prescription drug that results in the prescription drug being sold in the District for an excessive price" was preempted because it presented "a clear obstacle to the accomplishment and execution of the purpose and objectives set by Congress in passing federal patent laws relating to prescription drugs." *Id.* at 61. Under that statute, a prima facie case could be established by showing that the wholesale price of the drug in the District was over 30% higher than the comparable price in any of four high income countries. If that showing was made the burden shifted to the manufacturer to show the price was not excessive. The court concluded:

> In short, using the litigation process to determine on a drug to drug basis the application of a given drug's pricing vis a vis that in a foreign country directly interferes with, and second guesses, the balance set by Congress in the current system of patents and market exclusivity for pharmaceutical products. Moreover, by allowing foreign drug prices to serve as the benchmark by which excessiveness may be determined in this country, the City Council is effectively substituting Congress' regulatory scheme for this industry with the regulatory system that has been formulated by these enumerated foreign countries. Because Congress' judgment in this area is supreme, the D.C. Act is preempted and therefore facially unconstitutional.

Id. at 67.

On appeal, the Federal Circuit Court also relied on the legislative history of the Hatch-Waxman Act, specifically a statement by the House Committee on Energy and Commerce that:

> Patents are designed to promote innovation by providing the right to exclude others from making, using, or selling an invention. They enable innovators to obtain greater profits than could have been obtained if direct competition existed. These profits act as incentives for innovative activities.

Biotechnology Indus. Org. v. District of Columbia, 496 F.3d 1362, 1373 (Fed. Cir. 2007) citing H.R. Rep. No. 98–857, at 17 (1984), U.S. Code Cong. & Admin. News 1984, pp. 2647, 2650. The circuit court concluded that the District of Columbia law rebalanced the framework of rewards and incentives put in place by the patent law as it relates to inventive new drugs, and was "a clear attempt to restrain those excessive prices, in effect diminishing the reward to patentees in order to provide greater benefit to District drug consumers" and thus was preempted by federal patent law.

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[3] *But see Biotechnology Industry Org. v. District of Columbia,* 505 F.3d 1343, 1348 (Fed. Cir. 2007) (Dyk J., dissenting from denial of rehearing en banc).

Id. at 1374. The court subsequently denied a request for rehearing and request for rehearing en banc. *Biotechnology Industry Org.*, 505 F.3d at1351.

There is general agreement among commentators that the conclusion that the District of Columbia law was preempted was correct, but only because the law targeted only patented prescription drugs. *See* Christopher Lee Lockwood, *Biotechnology Industry Organization v. District of Columbia: A Preemptive Strike Against State Price Restrictions on Prescription Pharmaceuticals*, 19 Alb. L.J. Sci. & Tech. 143, 174-175 (2009); Serena Lipski, *Excessive Pricing and Pharmaceuticals: Why the Patent Act Does Not Preempt State Regulation of Pharmaceutical Prices*, 39 U. Tol. L. Rev. 913, 913-914 (2008). The same commentators, however, have criticized the conclusion that the law stood as an obstacle to the accomplishment and execution of the purposes and objectives of Congress and have taken the position that a law that applied more even-handedly should not be found to be preempted.

As a preliminary matter, there is the question of whether the *Biotechnology* court gave sufficient weight to the strong presumption against preemption with respect to exercises of the state police power in "fields of traditional state regulation" such as health and safety. *Biotechnology*, 515 F.3d at 1351 (Dyk, J., dissenting), citing *N.Y. State Conference of Blue Cross & Blue Shield Plans v. Travelers Ins. Co.*, 514 U.S. 645, 654-55 (1995). This presumption has long been applied in the patent context:

> Congress never intended that the patent laws should displace the police powers of the States, meaning by that term those powers by which the health, good order, peace, and general welfare of the community are promoted. Whatever rights are secured to inventors must be enjoyed in subordination to this general authority of the State over all property within its limits.

Webber v. Virginia, 103 U.S. 344, 347-48 (1880). Thus, where traditional areas of state concern such as health are involved the presumption is that they can "normally coexist with federal regulation," *Hillsborough County, Florida v. Automated Med. Labs., Inc.*, 471 U.S. 707, 718 (1985), and that such powers are not superseded by federal law unless it is shown that was the "clear and manifest purpose of Congress." *N.Y. State Conference*, 514 U.S. at 655. Control of prescription drug prices falls well within the state police power to protect public health. Serena Lipski, *Excessive Pricing and Pharmaceuticals: Why the Patent Act Does Not Preempt State Regulation of Pharmaceutical Prices*, 39 U. Tol. L. Rev. 913, 915-916 (2008); Christopher Lee Lockwood, *Biotechnology Industry Organization v. District of Columbia: A Preemptive Strike Against State Price Restrictions on Prescription Pharmaceuticals*, 19 Alb. L.J. Sci. & Tech. 143, 174 (2009); *see also* Brief of *amici curiae* of the AARP, *et al* in *Association for Accessible Medicines*, 2017 WL 6402859.

As discussed above, it has also been argued that the decision of the court in *Biotechnology* swept too broadly. In the absence of express or field preemption, a state statute that does not render compliance with federal law impossible should be found to be preempted only if it stands as an obstacle to the achievement of the goals of federal law. As stated by the Supreme Court in *Aronson v. Quick Point Pencil Co.*, 440 U.S. 257, 262 (1979):

> First, patent law seeks to foster and reward invention; second, it promotes disclosure of inventions to stimulate further innovation and to permit the public to practice the invention once the patent expires; third, the stringent requirements for patent protection seek to assure that ideas in the public domain remain there for the free use of the public.

The method chosen by Congress in the patent law is an exclusive right in the invention, "which . . . consists altogether in the right to exclude everyone from making, using, or vending the thing patented, without the permission of the patentee. This is all that [the patentee] obtains by the patent." *Bloomer v. McQuewan*, 55 U.S. (1 How.) 539, 548 (1852). Undoubtedly, this exclusive right may enable greater profit than if others could also make, use, and sell the patented item, but it does not guarantee a right to exploit the grant for the maximum profit that the market will bear. *Biotechnology*, 505 F.3d at 1350 (Dyk J. dissenting); Christopher Lee Lockwood, *Biotechnology Industry Organization v. District of Columbia: A Preemptive Strike Against State Price Restrictions on Prescription Pharmaceuticals*, 19 Alb. L.J. Sci. & Tech. 143, 171 (2009). Thus, "[b]eyond the limited monopoly which is granted, the arrangements by which the patent is utilized are subject to the general law." *United States v. Masonite Corp.*, 316 U.S. 265, 277 (1942) (patent law does not provide a shield from antitrust provisions of the Sherman Act). Nor would the Hatch-Waxman Act appear to change this conclusion. That Act extends the period of exclusivity, but contains nothing that would expand that right or grant rights against state regulation that were not already present. *See Biotechnology Industry Org.*, 505 F.3d at 1351 (Dyk, J., dissenting).

As such, a state may regulate a patented product as long as the state does not deprive the patentee of his or her federal property rights with regard to the patent. *See generally Patterson v. Kentucky*, 97 U.S. 501, 503-04 (1878) (concluding that a Kentucky regulation that prohibited the sale of a patented oil was within the power of the state, and that the patentee's property right in the patent was still intact). Price regulations are ordinarily understood to fall within the state police power. Christopher Lee Lockwood, *Biotechnology Industry Organization v. District of Columbia: A Preemptive Strike Against State Price Restrictions on Prescription Pharmaceuticals*, 19 Alb. L.J. Sci. & Tech. 143, 155 (2009). Many states have enacted price gouging laws, *id.* at 156, and other laws that "impede patent holders from exploiting their exclusive rights in order to derive above-market profits on their patented goods" such as state-wide bans on the sale and manufacture of certain goods, and products liability actions. *Id.* at 158; *see also Webber v. Virginia*, 103 U.S. 344, 347-48 (1880) (finding state tax not preempted as applied to sale of patented products); *Patterson v. Kentucky*, 97 U.S. 501 (1878) (holding patent rights subordinated to state statute governing safety requirements for lighting oil). In fact, while the dissent in *Biotechnology* argues that the majority opinion would preempt any state law regulating the prices of patented pharmaceutical products,[4] the concurrence in the case argues that the majority opinion relates only

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[4] Judge Dyk dissented from the denial of rehearing because he felt that the majority analysis was wrong and that field preemption should have applied again. He agreed with the majority, however, that the District of Columbia legislation was invalid. *Biotechnology Industry Org.*, 505 F.3d at 1348 (Dyk, J., dissenting).

to the situation at hand, suggesting that the same analysis would not apply to a statute that applied to all prescription drugs, and questions whether "future efforts of states to regulate drug prices, which for example did not only target patent drugs or did not as significantly or directly undermine the balance of the federal patent right, would also be preempted is a question that remains for another day." *Biotechnology*, 505 F.3d at 1348 (Gajarsa, J. concurring). Commentators have agreed that where "price controls do not negate the incentive given to patentees under the Patent Act, the Patent Act should not preempt price regulations." *See e.g.* Serena Lipski, *Excessive Pricing and Pharmaceuticals: Why the Patent Act Does Not Preempt State Regulation of Pharmaceutical Prices*, 39 U. Tol. L. Rev. 913, 935 (2008).

Unlike the District of Columbia law addressed in *Biotechnology*, the proposed legislation applies to all prescription medicines, whether subject to patent or not, though those covered by patents can have higher prices and larger increases before being identified by the Board on the basis of price. This fact alone could be adequate to save it from preemption unless the broader approach taken by the majority in *Biotechnology* is applied. In addition, the proposed legislation, unlike the District of Columbia law, does not control what a patent holder may charge, but what payors in the State may pay. In light of the criticism, and the views stated in the concurrence and dissent, it is possible that a court reviewing the proposed legislation would take an approach with more deference to the police powers of the state in the area of health and less weight on the possible burden on the exclusive rights of patent holders.

It is also possible, however, that the proposed legislation has aspects that may make it more vulnerable to patent challenges. The proposed legislation includes the manufacture's prices in the determination of excess costs, but includes the manufacturer's costs only if it reaches phase two of the analysis and there is no requirement that costs be considered in setting rates. Moreover, a major factor in determining excess costs is the cost of existing alternate therapies. Thus, while the manufacturer of a patented drug retains an exclusive right under the patent, rate setting may result in an upper limit based on the prices currently paid for nonpatent and generic drugs. Nevertheless, the proposed legislation does not grant any other person the ability to make a prescription drug that is protected by patent and would not interfere with the position of the patent holder as sole participant in an exclusive market for the drug. *Cf.*, Christopher Lee Lockwood, *Biotechnology Industry Organization v. District of Columbia: A Preemptive Strike Against State Price Restrictions on Prescription Pharmaceuticals*, 19 Alb. L.J. Sci. & Tech. 143, 176 (2009) Nor does it limit the overall amount of profit that pharmaceutical patent holders are permitted to collect in their exclusive markets. *Id.* at 176-177. Thus, it is my view that the proposed legislation could be upheld against a challenge under the Supremacy Clause based on the patent law.

SUPREMACY CLAUSE - ERISA

Finally, in *Pharm. Care Mgmt. Ass'n v. Gerhart*, 852 F.3d 722 (8th Cir. 2017), the court held that an Iowa law that regulated how pharmacy benefit managers established generic drug pricing, and required that pharmacy benefit managers disclose their drug pricing methods to network pharmacies and to the insurance commissioner was preempted by the Employee Retirement Income Security Act of 1974 ("ERISA"), 29 U.S.C. §§ 1001, et seq. *See also Pharmaceutical Care Management Association v. Rutledge*, 891 F.3d 1109 (8th Cir. 2018).

Specifically, the court found that the law had reference to and placed requirements on pharmacy benefit managers with respect to plans subject to ERISA and, as such, "intrude[d] upon a matter central to plan administration and interfere[d] with nationally uniform plan administration" in violation of the express preemption provision of ERISA. *Id.* at 730-731. The reasoning of this decision has been criticized, *See Pharmaceutical Care Management Association*, 326 F.Supp.3d 873 (D.N.D. 2018), and *Rutledge* is the subject of a petition for certiorari to the Supreme Court and the State of Maryland and 31 other states have joined a brief asking that the Supreme Court hear the case. *Brief for the States*, 2018 WL 6179405 (November 21, 2018). Nevertheless, should the *Gerhart/Rutledge* approach prevail, the application of the proposed law to pharmacy benefit managers for covered plans could be found to be preempted.[5]

In summary, it is my view that the proposed legislation would likely be upheld against a Commerce Clause challenge, and could be upheld against a Supremacy Clause challenge with respect to the patent law. Preemption under ERISA with respect to self-insured plans is likely, but would not affect the validity of the law with respect to other payors.

Sincerely,

Kathryn M. Rowe
Assistant Attorney General

KMR/kmr
pena-melnyk60

[5] In writing this letter I have not looked into the extent to which upper payment limits set by the Board would apply to Medicare and Medicaid. It may be that a waiver would be necessary or that the current waiver would cover this matter.