



May 18, 2016

Hon. Jose L. Báez Rivera Cámara de Representantes El Capitolio Apartado 9022228 San Juan, Puerto Rico 00902-2228

Dear Representative Báez Rivera:

The Antitrust Division of the U.S. Department of Justice (the "Division") and the staff of the Federal Trade Commission<sup>1</sup> (the "FTC") welcome the opportunity to share our views on Puerto Rico Senate Bill 991 (the "Bill"), which would expand the scope of practice for optometrists and allow them to use and prescribe medications to diagnose and treat diseases of the eye.<sup>2</sup> Currently, ophthalmologists in Puerto Rico have this authority.<sup>3</sup>

In commenting on the Bill, we recognize the critical importance of patient health and safety, and the responsibility of legislators and regulators in Puerto Rico to balance public policy priorities and define the appropriate scope of practice for medical professionals, including ophthalmologists and optometrists. At the same time, however, we have long observed that unnecessarily restrictive scope-of-practice laws can dampen competition and impose significant costs on

<sup>2</sup> P. del S. 991, 17<sup>th</sup> Asamblea Legislativa (P.R. 2014). All references that follow are based on a certified translation of the Spanish language version of the Bill.

<sup>3</sup> 20 L.P.R.A. § 544(b), 544(e) (2013) (prohibiting the "use of medication or surgery" in the practice of optometry in Puerto Rico, except for cycloplegic agents and topical anesthetics to determine the refractive condition of the eye). All aspects of eye and vision care, including surgery, can be provided by ophthalmologists, who are either doctors of medicine (M.D.) or osteopathy (D.O.).

<sup>&</sup>lt;sup>1</sup> This letter expresses the views of the FTC's Office of Policy Planning, Bureau of Competition, and Bureau of Economics. The letter does not necessarily represent the views of the FTC or any individual Commissioner. The Commission, however, has voted to authorize staff to submit these comments.

health care consumers and other payors. For this reason, we generally have encouraged legislatures to avoid restrictions that are not necessary to address well-founded patient safety concerns.<sup>4</sup> We write now to highlight the potential competitive benefits of loosening the prohibitions on Puerto Rican optometrists using or prescribing medications for treatment and diagnosis and to encourage the legislature to consider the procompetitive implications of expanding the scope–of-practice of optometrists in its consideration of the Bill.<sup>5</sup>

## I. The Agencies' Interest and Experience in Health Care Competition

Competition is a core organizing principle of America's economy,<sup>6</sup> and vigorous competition among sellers in an open marketplace gives consumers the benefits of lower prices, higher quality goods and services, increased access to goods and services, and greater innovation.<sup>7</sup> The FTC and the Division (the "Agencies") work to promote competition through shared enforcement of the antitrust laws, which prohibit certain transactions and business practices that harm competition and consumers, and through competition advocacy efforts, which urge decisions that benefit competition and consumers, whether through comments on legislation, discussions with regulators, or court filings, among other channels.

<sup>&</sup>lt;sup>4</sup> For example, the FTC staff's 2014 policy paper on regulation of advanced practice nurses details the competition concerns with unnecessarily restrictive scope-of-practice regulations and highlights the importance of independent prescription authority. *See* FED. TRADE COMM'N STAFF, POLICY PERSPECTIVES: COMPETITION AND THE REGULATION OF ADVANCED PRACTICE NURSES (2014), http://www.ftc.gov/system/files/documents/reports/policy-perspectives-competitionregulation-advanced-practice-nurses/140307aprnpolicypaper.pdf.

<sup>&</sup>lt;sup>5</sup> We confine our comments to the Bill's proposed expansion of the authority of optometrists to use and prescribe medications and its competitive effects.

<sup>&</sup>lt;sup>6</sup> See, e.g., N.C. State Bd. of Dental Exam'rs v. FTC, 135 S. Ct. 1101, 1109 (2015) ("Federal antitrust law is a central safeguard for the Nation's free market structures."); Standard Oil Co. v. FTC, 340 U.S. 231, 248 (1951) ("The heart of our national economic policy long has been faith in the value of competition.").

<sup>&</sup>lt;sup>7</sup> See, e.g., Nat'l Soc'y of Prof'l Eng'rs v. United States, 435 U.S. 679, 695 (1978) (noting that the antitrust laws reflect "a legislative judgment that ultimately competition will produce not only lower prices, but also better goods and services.... The assumption that competition is the best method of allocating resources in a free market recognizes that all elements of a bargain – quality, service, safety, and durability – and not just the immediate cost, are favorably affected by the free opportunity to select among alternative offers.").

Because health care competition is vitally important to the economy and consumer welfare, this sector has long been a priority for the Agencies.<sup>8</sup> Specifically, the Agencies have extensive experience investigating the competitive effects of mergers and business practices by hospitals, insurers, pharmaceutical companies, pharmacy benefit managers, physicians, and other providers of health care goods and services. The Agencies also have provided guidance to the health care community on the application of the antitrust laws and sponsored various workshops and studies to examine the health care industry. Finally, through competition advocacy, the Agencies have encouraged U.S. jurisdictions to consider the competitive impact of various health care-related legislative and regulatory proposals, including scope-of-practice restrictions.<sup>9</sup>

## II. Senate Bill 991

The Bill would expand the scope of practice with respect to the use of pharmacological agents for optometrists in Puerto Rico, provided they undergo additional training. Currently, ophthalmologists in Puerto Rico have the ability to use and prescribe medicine to treat and diagnose eye diseases. The Bill redefines the practice of optometry as the examination, diagnosis, and treatment of any illness, condition, or disorder of the human visual system, including the eye or adnexa.<sup>10</sup> Optometrists who pass a 120-hour course on the treatment and management of ophthalmic diseases would be authorized to perform additional functions and procedures.<sup>11</sup> In particular, these optometrists would be permitted to use pharmacological agents, including several categories of topical and oral

<sup>&</sup>lt;sup>8</sup> A description of, and links to, the FTC's various health care-related activities can be found at <u>https://www.ftc.gov/tips-advice/competition-guidance/industry-guidance/health-care</u>. An overview of the Division's health care-related activities is available at <u>http://www.justice.gov/atr/health-care</u>.

<sup>&</sup>lt;sup>9</sup> See, e.g., Letter from Marina Lao, Dir., Off. of Pol'y Planning, Fed. Trade Comm'n, & Robert Potter, Chief, Legal Pol'y Sec., Antitrust Div., U.S. Dep't of Justice, to Hon. Bradley H. Jones, Jr., Mass. House of Representatives (Feb. 18, 2016) (evaluating competitive considerations regarding Massachusetts legislation to lessen scope-of-practice restrictions on Massachusetts optometrists in the treatment of glaucoma), <u>https://www.justice.gov/opa/file/826371/download</u>; FED. TRADE COMM'N & U.S. DEP'T OF JUSTICE, IMPROVING HEALTH CARE: A DOSE OF COMPETITION, Ch. 2, 25–33 (July 2004), <u>http://www.usdoj.gov/atr/public/health\_care/204694.htm</u> (considering the competitive impact of licensing restrictions in health care).

<sup>&</sup>lt;sup>10</sup> *Compare* S.B. 991, § 1(a), *with* 20 L.P.R.A. § 544(a) (2013) (focusing its definition of optometry on correcting defects in vision).

<sup>&</sup>lt;sup>11</sup> S.B. 991, § 1(b)(7) (including 90 classroom hours and 30 clinical hours).

medications, to diagnose, treat, mitigate, and manage diseases of the eye.<sup>12</sup> No optometrists would be allowed to perform surgery.<sup>13</sup>

We also understand that, in all other states and U.S. territories, optometrists have authority under their scope-of-practice laws to prescribe at least some medications for the diagnosis and treatment of eye diseases.<sup>14</sup> In that respect, the Bill would conform the practice of optometry in Puerto Rico with scope-of-practice standards elsewhere in the United States.

## III. Competitive Considerations Regarding Senate Bill 991

We recognize that certain professional scope-of-practice regulations can be important to ensure quality and patient safety, and the regulation of eye care services is no exception. Competition that does not otherwise jeopardize patient safety, however, can bring important benefits to health care consumers. Generally, competition in health care markets benefits consumers by expanding access and choice, containing costs, and promoting innovation. Unnecessarily restrictive scope-of-practice laws can suppress these important benefits by limiting the supply of qualified care providers. Such a result may be particularly important in Puerto Rico, which, according to the Centers for Disease Control and Prevention, has the highest percentage of adults in the United States and its territories reporting severe difficulty seeing or blindness.<sup>15</sup>

The DOJ and FTC staff recommend that the legislature consider the potential benefits of enhanced competition among eye care providers that expanding the scope of practice of optometrists beyond current legal limits, and maintaining only those restrictions necessary to ensure patient health and safety,

<sup>13</sup> S.B. 991, § 1(b)(8).

<sup>&</sup>lt;sup>12</sup> S.B. 991, §§ 1(b)(5), 1(k)(1), 3(m), 3(o). We confine our comments to analyzing the use of pharmacological agents by optometrists. We note, however, that optometrists who complete the 120-hour course also would be permitted to perform certain additional non-surgical procedures, including removal of foreign bodies as long as the anatomical structure of the cornea, conjunctiva, or sclera has not been damaged; removal of eyelashes; nasal tip dilation; and punctum plug insertion. S.B. 991, § 1(b)(6).

<sup>&</sup>lt;sup>14</sup> See, e.g., NAT'L ASS'N OF BDS. OF PHARMACY, SURVEY OF PHARMACY LAW, 83-84 (2012) <u>https://pharmacy.uc.edu/admin/documents/2012%20Survey%20of%20Pharmacy%20Law.pdf</u> (listing the prescribing authority of optometrists in each U.S. state and territory).

<sup>&</sup>lt;sup>15</sup> See Vision & Eye Health Data & Maps, CENTERS FOR DISEASE CONTROL AND PREVENTION, http://nccd.cdc.gov/visionhealth/rdPage.aspx?rdReport=DDT\_VHI.ExploreByTopic&islTopic= <u>T04&islYear=2013</u> (last visited May 3, 2016).

could facilitate. Under current law unique to Puerto Rico, optometrists are broadly restricted from using or prescribing pharmacological agents for treatment and diagnosis.<sup>16</sup> Restrictions on optometrists' ability to use and prescribe pharmacological agents reduces the types and scope of services optometrists can provide to Puerto Rican consumers. For example, existing limitations on prescription authority can hamper optometrists' ability to treat certain eye diseases and conditions, including styes and eye infections. Additionally, as discussed below, such restrictions may inhibit efficient coordination and collaboration among health care providers.

We also urge the legislature to consider how additional competition among eye care providers could help to alleviate, in particular, two important barriers to the delivery of affordable eye care: access and cost. First, optometrists tend to be more convenient to visit than ophthalmologists. Across the United States, optometrists outnumber ophthalmologists, and counties in rural areas and other underserved communities tend to have fewer ophthalmologists.<sup>17</sup> Because optometrists see many patients for routine eye exams and optical care, they may be better positioned to serve as a more accessible first line of defense for many eye problems and ailments. Therefore, expanded scope of practice for optometrists in Puerto Rico may lead to earlier diagnosis and less costly treatment of certain conditions.

In addition, to the extent that optometrists and ophthalmologists serve as complementary eye care providers, expanded scope of practice for optometrists may foster more efficient coordination and collaboration with ophthalmologists and spur the development of innovative models of care delivery. For example, ophthalmologists may be able to focus their time on more complex cases, which may produce a better allocation of resources and yield better overall health outcomes for Puerto Rico's population.

Furthermore, certain patients may forgo or delay needed care if it is too costly. Allowing optometrists to compete by using and prescribing

<sup>&</sup>lt;sup>16</sup> See statute cited *supra* note 3 and accompanying text.

<sup>&</sup>lt;sup>17</sup> Diane M. Gibson, *The Geographic Distribution of Eye Care Providers in the United States: Implications for a National Strategy to Improve Vision Health,* 73 PREVENTIVE MED. 30, 31-32 (2015) (finding 17,793 ophthalmologists and 44,402 optometrists in the U.S. in 2011 and finding that U.S. counties with fewer ophthalmologists per capita had significantly lower population densities, larger proportions of rural residents, and higher proportions of residents aged 65 years and older). That pattern of distribution appears to hold in Puerto Rico, where public directories report 325 optometry offices compared with 118 ophthalmology offices. MEDICOSPR.COM, <a href="http://www.medicospr.com/">http://www.medicospr.com/</a> (last visited May 3, 2016).

pharmacological agents to diagnose and treat eye diseases, to a degree commensurate with their training, could help to ensure that more patients benefit from price competition and greater access to affordable providers.<sup>18</sup> Conversely, continued restrictions on optometrists' ability to write pharmacological prescriptions may limit price competition among providers who are capable of safely providing some comparable eye care services, to the detriment of health care consumers in Puerto Rico, especially those who are most cost-sensitive.

The experience of other jurisdictions may be informative as the legislature considers the Bill. We understand that Puerto Rico's educational and licensing requirements for optometrists are the same as those of other U.S. jurisdictions.<sup>19</sup> Yet, all states, the District of Columbia, and other U.S. territories currently grant licensed optometrists some authority to utilize and prescribe medications.<sup>20</sup> Some U.S. jurisdictions require additional training or certifications in order for optometrists to prescribe these medications, among other possible restrictions to ensure patient safety; the Bill likewise proposes certain requirements.<sup>21</sup> Thus,

<sup>19</sup> For example, to obtain an optometry license in Puerto Rico, as in other jurisdictions, applicants must have a Doctor of Optometry degree from an academic institution accredited by the Council of Optometric Education of the American Optometric Association. Likewise, optometrists seeking to practice in Puerto Rico must pass examinations administered by the National Board of Examiners in Optometry. 20 L.P.R.A. § 544(i)(3)-(4) (2013). *See also* S.B. 991 (Statement of Purpose).

<sup>20</sup> See, e.g., NAT'L ASS'N OF BDS. OF PHARMACY, *supra* note 14, at 83-84.

<sup>&</sup>lt;sup>18</sup> See, e.g., New Hampshire Ins. Dep't, Payment Differences in Reimbursement to Ophthalmologists and Optometrists (2013),

<sup>&</sup>lt;u>https://www.nh.gov/insurance/reports/documents/diff\_reimb\_optha\_optom.pdf.</u> This report compares charges and payments for procedures performed by optometrists and ophthalmologists. For example, for certain medical examinations and evaluations, payments to ophthalmologists exceeded payments to optometrists anywhere from 19 percent to 64 percent. *See also* Mordachai Soroka, *Comparison of Examination Fees and Availability of Routine Vision Care by Optometrists and Ophthalmologists*, 106 PUB. HEALTH REP. 455, 457–59 (1991) (comparing examination fees and appointment availability between optometrists and ophthalmologists).

<sup>&</sup>lt;sup>21</sup> For example, in order to use and prescribe therapeutic pharmaceutical agents, Guam requires optometrists to complete coursework, including supervised clinical training, offered by an accredited institution on the examination, diagnosis, and treatment of eye conditions. GUAM CODE ANN. TIT. 10, § 12508 (2015). The U.S. Virgin Islands requires, in certain circumstances, optometrists to complete 100 classroom hours and 30 clinical hours of training on specific pharmacological agents. V.I. CODE ANN. TIT. 27, § 161 (2014). As an example of other conditions to ensure patient safety, American Samoa requires referrals to physicians when "appropriate . . . for the medical diagnosis and treatment of abnormal conditions." AM. SAMOA CODE ANN. § 31.0403(i) (2011).

relaxing Puerto Rico's prohibition on optometrists' use of pharmacological agents, subject to requirements the legislature finds appropriate to ensure patient safety, would be consistent with prescription authority granted to optometrists elsewhere in the United States.<sup>22</sup>

## IV. Conclusion

Competition among health care professionals benefits consumers by improving access to care, containing costs, and encouraging more ways to deliver needed care. By allowing optometrists to provide eye care services with pharmacological agents to a degree commensurate with their training, consumers in Puerto Rico may experience greater access to care, more costeffective treatment, and more choice in how their care is delivered. Because these benefits could be significant, we encourage the legislature to carefully consider relaxing the prohibition on optometrists' utilizing and dispensing of pharmacological agents.

We appreciate this opportunity to present our views.

Marina Lao, Director Office of Policy Planning Federal Trade Commission Robert Potter, Chief Legal Policy Section Antitrust Division U.S. Department of Justice

<sup>&</sup>lt;sup>22</sup> See NAT'L ASS'N OF BDS. OF PHARMACY, supra note 14, at 83–84.