COMMONWEALTH OF MASSACHUSETTS

SUFFOLK, ss

SUPERIOR COURT
CIVIL ACTION NO. 2014-2201-A

WILLIAM H. DOWNING, SANDRA J. HOLWAY, WHITNEY GRUNWALD, CHERYL D. MARSHALL, DANIEL F. LAMBERT, RICHARD S. HAMPTON, MARK JAQUITH, PATRICK FLAHERTY, BRIAN BEELER, MICHAEL GLENN, VINCENT ZERUESKES, BARRY R. LEVINE, EDWARD LEGER, DENISE DEANGELIS, TANYA ROWE, and DAVID L. TAMARIN,

Plaintiffs,

v.

DEPARTMENT OF PUBLIC HEALTH and CHERYL BARTLETT, THE COMMISSIONER OF PUBLIC HEALTH,

Defendants.

DEFENDANTS' OPPOSITION TO PLAINTIFFS' APPLICATION FOR TEMPORARY RESTRAINING ORDER

Defendants, the Department of Public Health ("DPH") and Cheryl Bartlett, the Commissioner of DPH, hereby oppose plaintiffs' Application for Temporary Restraining Order.

INTRODUCTION

This case involves a ballot initiative approved by the voters of Massachusetts in November 2012, *An Act for the Humanitarian Medical Use of Marijuana*, St. 2012, c. 369, §§ 1 to 17, codified at G.L. c. 94C, App. §§ 1-1 to 1-17 (the "Act"), and regulations promulgated by DPH pursuant to its authority under the Act, 105 C.M.R. §§ 725.001 to 725.800. The plaintiffs are William H. Downing—who seeks to cultivate and distribute medical marijuana as a "personal caregiver" to over 1,000 qualifying patients—and 15 of those patients (the "patient-plaintiffs"). Plaintiffs challenge three aspects of DPH's regulations under the Act: (1) the limitation on a "personal caregiver" authorized to procure and, in some instances, to grow,

marijuana for a qualifying patient, that such an individual may serve in that capacity for only one qualifying patient, 105 C.M.R. § 725.020(D); (2) the prohibition on a personal caregiver receiving compensation for services rendered other than reimbursement for reasonable expenses incurred as a caregiver, *id.* § 725.020(G); and (3) the imposition of fees upon qualifying patients, pursuant to a fee schedule implemented by DPH in accordance with its regulations. Complaint for Declaratory and Injunctive Relief ("Compl.") at pp. 11-12 (Prayer for Relief). Plaintiffs claim that DPH's regulations violate certain of their constitutional rights—specifically their right to associate and "their constitutional and statutory right to medicate with a physician's recommendation", *id.* at p. 11—and exceed DPH's authority under the Act.

Plaintiffs have applied for a temporary restraining order, asking this Court to order DPH to "cease notifying Qualified Patients that William H. Downing may not serve them as their designated caregiver", and to "suspend application" of DPH's regulations to Downing's activities as a designated caregiver. Application for Temporary Restraining Order ("Application") at 1. They seek such a restraining order until at least August 27, 2014, when plaintiffs propose that this Court hold a hearing on a motion for a preliminary injunction. *See* Memorandum in Support of Motion for Temporary Restraining Order ("TRO Mem.") at 1.

Plaintiffs' request for a restraining order should be denied. First, plaintiffs ask this Court to enjoin DPH's regulations until a hearing at least 45 days from now. But a temporary restraining order may not last longer than 10 days under Mass. R. Civ. P. 65(a). Second, plaintiffs claim that granting a TRO is necessary to preserve the status quo, but their motion does no such thing—instead it would create a substantial exception to the normal statutory and regulatory requirement that large-scale cultivation and distribution of medical marijuana for qualifying patients take place only at dispensaries licensed by DPH. In effect, plaintiffs are seeking relief of a kind ordinarily available only through a motion for preliminary injunction, but

they seek to evade the preliminary injunction standard by calling their motion one for a temporary restraining order.

Should this Court elect to treat plaintiffs' motion as a request for a preliminary injunction, the motion should similarly be denied. Plaintiffs—and in particular Downing—seek to sidestep the carefully-delineated statutory and regulatory process for licensed medical marijuana dispensaries authorized to sell and distribute medical marijuana to qualifying patients, essentially asserting that the Act's limited exception for cultivation of marijuana by a patient's "personal caregiver" gives Downing the authority to cultivate medical marijuana for more than 1,000 individuals, and to get paid for doing so. Downing's request, if granted, would effectively grant him the status of a medical marijuana dispensary, even though the Act and DPH's regulations create a clear distinction between medical marijuana dispensaries, on one hand, and personal caregivers, on the other, subjecting the former to elaborate licensing, inspection, and other requirements that Downing has not met.

Plaintiffs have not demonstrated that their facial challenge to DPH's regulations is likely to succeed on the merits. Rather, DPH's personal caregiver and fee regulations carefully and effectively implement the voters' intent to create a narrow exception for personal cultivation in circumstances of hardship from the general requirement that cultivation and distribution be undertaken only by closely-regulated marijuana dispensaries. Additionally, the harm to the public interest from allowing plaintiffs' motion—the creation of a largely unregulated market for cultivation and distribution of medical marijuana—is patent, and outweighs any harm that would result to plaintiffs from its denial, especially since the patient-plaintiffs remain free to designate another personal caregiver to procure and, if necessary, to cultivate their personal supply of medical marijuana. Plaintiffs' motion should therefore be denied.

BACKGROUND

Statutory and Regulatory Background

Massachusetts law generally prohibits the distribution or cultivation of marijuana. *See* G.L. c. 94C, § 32C.[1] On November 6, 2012, however, the voters approved the Act, which permits, under limited circumstances, the medical use of marijuana by qualifying patients under state law. The Act states as its purpose "that there should be no punishment under state law for qualifying patients, physicians and health care professionals, personal caregivers for patients, or medical marijuana treatment center agents for the medical use of marijuana." Act § 1.[2]

The Act delineates the specific circumstances under which medical use of marijuana is permissible under state law. Only a qualifying patient who has been diagnosed by a licensed physician as having a debilitating medical condition—such as cancer, HIV, AIDS, glaucoma, Parkinson's disease, or a similar condition, Act § 2(C)—may engage in the medical use of marijuana. *Id.* § 4. Such qualifying patients generally must obtain medical marijuana from medical marijuana dispensaries licensed by DPH. *See id.* § 9.[3] Section 9 of the Act requires these dispensaries to register with DPH, pay an application fee, submit a detailed application to DPH, and comply with DPH oversight rules. *Id.* § 9(A), (B). The Act authorizes DPH to promulgate regulations governing dispensaries, *id.* § 13, and pursuant to this authority DPH has promulgated extensive regulations—not challenged here—that govern the application and registration process for dispensaries, 105 C.M.R. §§ 725.100, 725.400, the operational

[1] Federal law similarly prohibits the distribution or cultivation of marijuana. *See* 21 U.S.C. § 841.

[2] The Act will be cited herein as "Act § [section number]", corresponding to the provisions of the General Laws codified at G.L. c. 94C, App. § 1-[section number]. So, for example, G.L. c. 94C, App. § 1-11 will be cited as "Act § 11".

[3] Medical marijuana dispensaries are referred to as "medical marijuana treatment centers" in the Act, *id.* § 9, and as "registered marijuana dispensaries", or "RMDs", in DPH's regulations, *see, e.g.*, 105 C.M.R. § 725.004. For the sake of consistency, this opposition refers to such facilities as "dispensaries".

requirements for dispensaries, *id.* § 725.105, security measures to prevent unauthorized access to dispensaries, *id.* § 725.110, and inspections by DPH of dispensaries, *id.* § 725.300.[4] Under the Act, DPH may only register a limited number of dispensaries in the Commonwealth—35 in all, and only between one and five in each county—unless it determines that the number of dispensaries is insufficient to meet patient needs. Act § 9(C). The Act also regulates "dispensary agents" who work at the dispensaries, requiring that they register with DPH; the Act prohibits individuals who have been convicted of felony drug offenses from serving as dispensary agents. *Id.* § 10; *see also* 105 C.M.R. § 725.030. DPH must also set application fees for dispensaries "to defray the administrative costs of the medical marijuana program and thereby make this law revenue neutral." Act § 13.

Section 11 of the Act creates a "hardship cultivation" exception to the usual rule that qualifying patients must obtain their medical marijuana from registered dispensaries. It states that qualifying patients "whose access to a [dispensary] is limited by verified financial hardship, a physical incapacity to access reasonable transportation, or the lack of a [dispensary] within a reasonable distance of the patient's residence" may obtain a cultivation registration, which "shall allow the patient or the patient's personal caregiver to cultivate a limited number of plants, sufficient to maintain a 60-day supply of marijuana, and shall require cultivation and storage only in an enclosed, locked facility." Act § 11. The Act defines a "personal caregiver" as "a person who is at least twenty-one (21) years old who has agreed to assist with a qualifying patient's medical use of marijuana"; a personal caregiver may not consume the marijuana

[4] *See also* 105 C.M.R. §§ 725.200(D) (imposing strict confidentiality requirements on dispensaries), 725.305 (authorizing DPH to issue "deficiency statements" to noncompliant dispensaries after DPH inspections), 725.310 (requiring noncompliant dispensary to submit detailed plan of correction for violations cited in deficiency statement), 725.405 (listing grounds for denial of dispensary renewal applications and registration revocation), 725.410 (listing circumstances that void dispensary registration), 725.415 (imposing limitations on dispensary marijuana sales), 725.445 (authorizing DPH to issue summary cease and desist order or quarantine order to dispensaries to protect public health, safety, or welfare).

obtained for the personal, medical use of the qualifying patient. *Id.* § 2(J). The qualifying patient must provide DPH with the name and address of his or her personal caregiver, if any. *Id.* § 12(A)(2)(b). The Act requires DPH to promulgate regulations to implement the hardship cultivation provision, *id.* § 11, and, more generally, to implement the requirements of Sections 9 through 12 of the Act, *id.* § 13.

Pursuant to these statutory directives, DPH promulgated regulations implementing the various requirements of the Act. *See generally* 105 C.M.R. §§ 725.001 to 725.800. As noted above, DPH's regulations provide for extensive regulation of dispensaries and their agents. *See* pages 4-5 and note 4, above. Also, in accordance with the directive from the Act (§ 13) and its regulations, DPH has implemented a fee schedule for dispensary applications and registrations, and for patient registration and hardship cultivation registration. Commonwealth of Massachusetts, Department of Public Health, Fee Structure for Medical Use of Marijuana Program (Aug. 6, 2013) ("Fee Structure").[5]

DPH's regulations also implement the Act's narrow exception for hardship cultivation or delivery of marijuana by personal caregivers. *See* 105 C.M.R. §§ 725.020 (requiring patients' registration of personal caregivers), 725.025 (detailing responsibilities of personal caregivers), 725.035 (regulating hardship cultivation registrations). Under these regulations, as under the Act, in the listed circumstances of hardship a qualifying patient or his or her personal caregivers may cultivate only "a limited number of plants sufficient to maintain a 60-day supply of marijuana solely for that patient's use". *Id*. § 725.035(G); *accord* Act § 11. Except for professional caregivers (such as hospice providers or home health aides) or family members of qualifying patients, "an individual may not serve as a personal caregiver for more than one

[5] A copy of the Fee Structure is attached as **Exhibit A** to this opposition.

registered qualifying patient at one time." *Id.* § 725.020(D). Each qualifying patient may designate up to two personal caregivers, who may cultivate marijuana on behalf of the patient at a single location. *Id.* § 725.020(E).[6] Additionally, personal caregivers "may not receive payment or other compensation for services rendered as a personal caregiver other than reimbursement for reasonable expenses incurred in the provision of services as a caregiver, provided however that a caregiver's time is not considered a reasonable expense." *Id.* § 725.020(G).

During the notice-and-comment process prior to final promulgation of these regulations, DPH received comments "primarily from individuals who seek to enter the market as personal caregivers" objecting to DPH's initial draft regulations insofar as they restricted personal caregivers to serving only one qualifying patient without compensation. Memorandum from the DPH Medical Marijuana Work Group to Interim Commissioner Lauren Smith and Members of Public Health Council at 11 (May 8, 2013) ("DPH Memorandum").[7] In rejecting these comments and maintaining the one-patient limitation, DPH explained that it "believes firmly that allowing a model of caregivers proposed in these comments"—*i.e.*, caregivers permitted to serve multiple individuals and to receive compensation for doing so beyond reimbursement for reasonable expenses incurred—"is not consistent with the intent of the [Act], which requires that an entity that cultivates, transfers, or dispenses medical marijuana is a MMTC [*i.e.*, a dispensary]." *Id.* DPH also explained that one of the purposes of its hardship cultivation regulation "is to minimize home-cultivation through stringent caregiver provisions" and other restrictions. *Id.* at 2. In other words, DPH explained that its aim in promulgating these

[6] Professional caregivers—such as hospice providers or home health aides—who serve as personal caregivers for qualified patients may not cultivate marijuana for those patients. 105 C.M.R. § 725.025(C).

[7] A copy of the DPH Memorandum is attached as **Exhibit B** to this opposition.

regulations was to preserve the Act's distinction between, on the one hand, larger-scale cultivation and distribution by registered marijuana dispensaries that are subject to pervasive regulation, inspection, and control, and, on the other hand, limited home cultivation of only a 60-day supply by a qualifying patient or his or her personal caregiver in instances of hardship. *See id.* at 2, 10-11.

Finally, to cover the costs of registration and comply with the Act's "revenue neutral" mandate (§ 13), the DPH Regulations and the Fee Structure require qualifying patients to pay a registration fee of $50, a fee of $10 to replace a registration card, and a fee of $100 to obtain a hardship cultivation registration, unless the patient demonstrates that the applicable fee poses a verified financial hardship. 105 C.M.R. §§ 725.015(A)(7), 725.035(B)(1); Fee Structure.

Factual and Procedural Background

Downing, the lead plaintiff in this action, is the principal of Care Givers Connection, LLC, doing business as Yankee Care Givers, and claims to have been designated as the personal caregiver by "over 1000 persons" who are qualifying patients. Compl. ¶¶ 1, 22. On June 25, 2014, DPH sent a letter to Downing notifying him that he may not serve as a personal caregiver for more than one registered qualifying patient at one time, ordering him to cease and desist serving as a personal caregiver, and deeming invalid his personal caregiver "registration card", effective immediately. Compl. ¶ 44. The same day, DPH sent letters to individuals who had identified Downing as their personal caregiver, including the patient-plaintiffs, notifying them that Downing can no longer serve as their personal caregiver because he is the designated personal caregiver of more than one person, in violation of DPH's regulations, but clarifying that the patients themselves are not considered to be in violation of the regulations due to Downing's

actions. Compl. ¶ 43. The patient letters informed the qualifying patients that "[u]ntil dispensaries become operational, you may choose a new personal caregiver". *Id.*[8]

Plaintiffs seek to enjoin or declare invalid DPH's regulations insofar as they limit a personal caregiver to serving only one person without compensation (other than reimbursement for reasonable expenses incurred) and impose registration application fees to qualifying patients to cover the cost of processing such applications. *See* Compl. at pp. 11-12 (Prayer for Relief). Plaintiffs have filed a TRO Application, seeking an order requiring DPH to (1) cease notifying qualifying patients that Downing may not serve as their designated caregiver; and (2) suspend application of 105 C.M.R. § 725.020(D) and (G) to Downing's activities as a designated caregiver. Application at 1.[9]

ARGUMENT

I. Plaintiffs Are Not Entitled to a Temporary Restraining Order.

Plaintiffs have labeled the papers currently before the Court as an Application for a Temporary Restraining Order, seeking an order "designed to preserve the status quo" until at least 45 days from now, when plaintiffs propose that this Court hold a hearing on their forthcoming motion for a preliminary injunction. TRO Mem. at 4; *see id.* at 1 (proposing that this Court hold a subsequent hearing on August 27, 2014). As an initial matter, plaintiffs cannot use the TRO provision of Mass. R. Civ. P. 65(a) to obtain an injunction of 45 days or longer, as any temporary restraining order entered by this Court would expire after a period "not to exceed 10 days" after entry. *Id.*; *see Royal Dynasty, Inc. v. Chin*, 37 Mass. App. Ct. 171, 173 (1994)

[8] Copies of the June 25, 2014, letter from DPH to Downing, and a representative June 25, 2014, letter from DPH to one of the patient-plaintiffs, are attached as **Exhibit C** to this opposition.

[9] Plaintiffs commenced this action on July 3, 2014, in the Supreme Judicial Court for Suffolk County. No. SJ-2014-0264. On July 8, 2014, a Single Justice of the Supreme Judicial Court (Spina, J.) entered an order transferring the case to this Court pursuant to G.L. c. 211, § 4A.

(temporary restraining orders under rule 65(a) "expire in ten days at the most"). Moreover, plaintiffs claim that one of the "elements" of a TRO is that it "preserve the status quo" until the parties may be heard on a motion for preliminary injunction. TRO Mem. at 3-4. But the Application would not preserve the status quo, except insofar as plaintiffs characterize the status quo as Downing's continuing violation of DPH regulations. To the contrary, plaintiffs seek to create an exception to the carefully crafted statutory and regulatory scheme that currently governs the cultivation and distribution of medical marijuana—an exception that would, in effect, allow Downing to operate as a *de facto* marijuana dispensary under the guise of acting as a "personal caregiver." *See, e.g.*, Act §§ 9-10 (specifying registration requirements for dispensaries and their agents); 105 C.M.R. §§ 725.100, 725.105, 725.110, 725.200(D), 725.300, 725.305, 725.310, 725.400, 725.405, 725.410, 725.445 (detailing application procedures for and restrictions on registered marijuana dispensaries).

In effect, plaintiffs are seeking a preliminary injunction—both in duration and in terms of enjoining the enforcement of DPH regulations that would otherwise clearly bar Downing's conduct—while claiming that Rule 65(a) entitles them to such relief under a less exacting standard than is ordinarily required for a preliminary injunction. *See* TRO Mem. at 4 (claiming entitlement to a TRO so long as plaintiffs demonstrate "irreparable injury" and preservation of the status quo); *id.* at 9 (stating that "Rule 65(a) does not require the applicant to show likelihood of success on the merits, as required for a preliminary injunction"). Plaintiffs are not entitled to the temporary restraining order they seek, and their request to this Court should instead be reviewed as a motion for a preliminary injunction.

II. Plaintiffs Are Not Entitled to a Preliminary Injunction.

Evaluated under the preliminary injunction standard, plaintiffs' motion fails as well. "[T]he significant remedy of a preliminary injunction should not be granted unless the plaintiffs

[make] a clear showing of entitlement thereto." *Student No. 9 v. Board of Educ*., 440 Mass. 752, 762 (2004). Plaintiffs are not entitled to preliminary injunctive relief unless they show: "(1) a likelihood of success on the merits; (2) that irreparable harm will result from denial of the injunction; and (3) that, in light of the [moving party's] likelihood of success on the merits, the risk of irreparable harm to the [moving party] outweighs the potential harm to the [nonmoving party] in granting the injunction." *Loyal Order of Moose, Inc., Yarmouth Lodge # 2270 v. Board of Health of Yarmouth*, 439 Mass. 597, 601 (2003) (quoting *Tri-Nel Mgt., Inc. v. Board of Health of Barnstable*, 433 Mass. 217, 219 (2001)); *Packaging Indus. Group, Inc. v. Cheney*, 380 Mass. 609, 616 (1980). In addition, because plaintiffs seek "to enjoin governmental action, the [Court] must also consider whether the grant of an injunction would adversely affect the public interest." *Student No. 9*, 440 Mass. at 762. Because plaintiffs cannot succeed on the merits of their claims, and because any harm to plaintiffs caused by continued enforcement of DPH's regulations would be far outweighed by the harm to the public in the event the challenged regulations are struck down, the Court should deny plaintiffs' request for an injunction.

A. Plaintiffs Are Unlikely to Succeed on the Merits Because the DPH Regulations Are Consistent with and Further the Purposes of the Act, and Because the DPH Regulations Do Not Infringe on Any of Plaintiffs' Constitutional Rights.

Plaintiffs have failed to demonstrate any likelihood of success on the merits, which is the "most important" part of the preliminary injunction inquiry. *E.g.*, *Pompei v. Fincham*, No. 07-4743-BLS2, 2007 WL 4626915, at *1 (Mass. Super. Ct. Nov. 16, 2007) (Fabricant, J.); *accord Sindicato Puertorriqueno de Trabajadores v. Fortuno*, 699 F.3d 1, 7 (1st Cir. 2012) ("[W]e have repeatedly held that [likelihood of success on the merits] is the most important part of the preliminary injunction assessment.") (citations and internal quotation marks omitted). Indeed, plaintiffs fail to state in their Complaint *any* causes of action whatsoever. *See generally* Compl.

Only in their prayer for relief do plaintiffs appear to assert that DPH's regulations exceed the agency's authority under the Act and violate plaintiffs' constitutional rights insofar as they (1) limit a personal caregiver such as Downing to serving in that capacity for only one individual (with exceptions not relevant here), 105 C.M.R. § 725.020(D); (2) prohibit a personal caregiver from receiving compensation (other than reimbursement for reasonable expenses incurred), *id.* § 725.020(G); and (3) impose modest registration fees for qualifying patients and for hardship cultivators, *id.* §§ 725.015(A)(7), 725.035(B)(1); Fee Structure. *See* Compl. at pp. 11-12.

Plaintiffs shoulder "a formidable burden" when they seek a declaration that regulations related to public health and safety are void, as they do here by seeking to invalidate the DPH regulations at issue. *Greenleaf Finance Co. v. Small Loans Regulatory Board*, 377 Mass. 282, 293 (1979); *see also, e.g.*, *Professional Fire Fighters of Mass. v. Commonwealth*, 72 Mass. App. Ct. 66, 80 (2008) ("[A]n assault against the validity of a public safety regulation encounters a strong battery of administrative law canons deployed among familiar precedents"). The standard of review of such regulations is "extraordinarily deferential" to the agency. *Id.* at 80. This Court "must apply all rational presumptions in favor of the validity of the administrative action" and "accord these regulations the same deference [it] extend[s] to statutes." *Thomas v. Commissioner of the Div. of Med. Assistance*, 425 Mass. 738, 746 (1997). "This deference is necessary to maintain the separation between the powers of the Legislature"—or, in this case, the voters—"and administrative agencies and the powers of the judiciary." *Borden, Inc. v. Commissioner of Pub. Health*, 388 Mass. 707, 723 (1983).

Thus, plaintiffs here must "prov[e] on the record 'the absence of any conceivable ground upon which [the rule] may be upheld.'" *Purity Supreme, Inc. v. Attorney General*, 380 Mass. 762, 776 (1980) (quoting *Colella v. State Racing Comm'n*, 360 Mass. 152, 156 (1971)). "[A] regulation . . . need not necessarily find support in a particular section of [the enabling statute]; it

is enough if it carries out the scheme or design of the chapter and is thus consistent with it." *Pepin v. Division of Fisheries & Wildlif*e, 467 Mass. 210, 222 (2014) (citations omitted); *see also Consolidated Cigar Corp. v. Department of Pub. Health*, 372 Mass. 844, 855 (1977) (regulation need only be "reasonably related to the purposes of the enabling legislation"). Indeed, "[r]egulations are not to be declared void unless their provisions cannot by any reasonable construction be interpreted in harmony with the legislative mandate, and enforcement of such regulations should be refused only if they are plainly in excess of legislative power." *Berrios v. Department of Pub. Welfare*, 411 Mass. 587, 595-96 (1992). For the reasons that follow, plaintiffs cannot satisfy these exacting requirements here.

1. The Challenged DPH Regulations Are Fully Consistent With The Act, Which They Implement.

DPH acted consistently with, and in direct furtherance of, the Act in promulgating the regulations limiting personal caregivers to serving one qualifying patient without compensation, 105 C.M.R. § 725.025(D) and (G), because both the language and structure of the Act contemplate that hardship cultivation by a personal caregiver is a limited, small-scale exception to the heavily-regulated, larger-scale cultivation and distribution of medical marijuana only by registered marijuana dispensaries. *See Commonwealth v. Cruz*, 459 Mass. 459, 464-65 (2011) (noting that analysis of ballot initiative "must give effect to the clear intent of the people of the Commonwealth" as deciphered from its plain language and statutory scheme).

As an initial matter, the plain meaning of the statutory term "*personal* caregiver" belies the notion that the voters intended any single personal caregiver to cultivate marijuana for over 1,000 qualifying patients, as Downing proposes to do here. Act §§ 2(J), 11 (emphasis added); *see, e.g.*, American Heritage Dictionary (2d ed. 1991) (definition of "personal" includes "[o]f or pertaining to a particular person; private; one's own" and "[c]oncerning a particular individual

and his intimate affairs, interests, or activities"); G.L. c. 4, § 6 (statutory "[w]ords and phrases shall be construed according to the common and approved usage of the language"). Further, the Act's hardship cultivation exception emphasizes the limited cultivation that qualifying patients or their personal caregivers may undertake in circumstances of hardship, "allow[ing] the patient or the patient's personal caregiver to cultivate *a limited number of plants*, sufficient to maintain *a 60-day supply* of marijuana." Act § 11 (emphases added); *see also* 105 C.M.R. § 725.035(G).

Instead, as recognized by DPH in promulgating the regulations at issue, the Act "requires that an entity that cultivates, transfers, or dispenses of medical marijuana is a MMTC [*i.e.*, a dispensary]." DPH Memorandum at 11. More specifically, the Act contemplates that larger-scale medical marijuana cultivation and distribution—of the kind that Downing has undertaken and seeks to continue—will occur *only* at a limited number of heavily-regulated registered marijuana dispensaries. *See, e.g.*, Act §§ 9(A), (B) (requiring dispensaries to pay fee and comply with DPH oversight rules and regulating dispensaries' principal officers and board members), 9(C) (limiting number of dispensaries to 35, with at least one but no more than five in each county), 10 (detailing restrictions on dispensary agents employed by dispensaries, including registration requirements, criminal background checks, treatment center notification requirements, and limitation that no one who has been convicted of a felony drug offense may serve as a dispensary agent).

DPH promulgated the challenged regulations pursuant to the Act's clear mandate to issue regulations that are "consistent with" the Act's hardship cultivation provisions specifically, Act § 11, and the Act's provisions for dispensaries, dispensary agents, qualifying patients, and designated caregivers more generally, *id.* § 13. *See Professional Fire Fighters of Mass.*, 72 Mass. App. Ct. at 80 ("An agency . . . may define the legislation more precisely by regulation."). The DPH regulations, as a whole, maintain the Act's focus on closely regulating marijuana

dispensaries, while allowing a limited exception for small-scale cultivation by qualifying patients or their personal caregivers.[10] The regulations challenged by plaintiffs in this action are an integral part of this statutory and regulatory scheme, in that they prevent largely unregulated personal caregivers from doing *exactly* what plaintiff Downing seeks to do here—to provide marijuana to thousands of individuals and to get paid for doing so, acting as a *de facto* dispensary without having to go through the comprehensive application and certification process, and without being subject to the extensive operation, inspection, remediation, and confidentiality requirements applicable to dispensaries. Plaintiffs' proposed reading of the Act flouts the voters' clear intent to lift the general prohibitions on cultivation and distribution of marijuana only under the specific and limited circumstances delineated by the Act. *See* G.L. c. 94C, § 32C; Act § 1.

Plaintiffs' challenge to the registration fee requirements set forth in DPH's regulations and the Fee Structure fares no better. DPH imposed these fees in furtherance of the voters' expressed intent "to make the law revenue neutral," ensuring that those utilizing the medical marijuana program, and not the Commonwealth's taxpayers, cover its expenses. Act § 13. Indeed, it has long been the law that "an express statutory grant to a[n] . . . agency of authority to regulate includes authorization to require licenses and licensing fees 'to cover reasonable expenses incident to the enforcement of the rules.'" *Southview Coop. Hous. Corp. v. Rent Control Bd. of Cambridge*, 396 Mass. 395, 400 (1985) (quoting *Commonwealth v. Plaisted*, 148 Mass. 375, 382 (1889)); *accord Opinion of the Justices*, 250 Mass. 591, 602 (1924), *Commonwealth v. Clay*, 224 Mass. 271, 274 (1916). The modest fees challenged here—$50 to

[10] *Compare, e.g.*, 105 C.M.R. §§ 725.100 to 725.415, 725.445 (detailing requirements for dispensary application fees, registration, operation, security, confidentiality, inspection, deficiency statements, and violation correction plans; listing grounds for denial of initial and renewal dispensary applications; describing circumstances that void dispensary registrations; limiting sale of marijuana by registered dispensaries; and providing for issuance of cease and desist orders to dispensaries to protect public health, safety, and welfare), *with id.* §§ 725.020, 725.025, 725.035 (detailing limitations on and responsibilities of personal caregivers and requirements for obtaining hardship cultivation registration).

obtain a registration card, $10 to replace a registration card, and $100 to obtain a hardship cultivation registration—are commensurate with, and help to defray, the administrative costs to DPH of reviewing registration applications, replacing registration cards, and reviewing hardship cultivation registrations, respectively. Thus, plaintiffs cannot demonstrate that they are likely to succeed on the merits of their challenge to the DPH regulations at issue here as ultra vires.

2. The Regulations at Issue Here Do Not Infringe on Any of Plaintiffs' Constitutional Rights.

The plaintiffs also cannot establish any likelihood of success on the merits on their putative constitutional claims. In their prayer for relief, plaintiffs seek a declaration that the regulations' limitations on personal caregivers "violate[] the constitutional rights of [q]ualified [p]atients to associate with the caregiver they choose," Compl. at p. 11, apparently invoking the constitutional freedom of association. Courts "have long understood as implicit in the right to engage in activities protected by the First Amendment a corresponding right to associate with others in pursuit of a wide variety of political, social, economic, educational, religious, and cultural ends." *Roberts v. U.S. Jaycees*, 468 U.S. 609, 622 (1984). This freedom "encompasses 'the right to enter into and maintain certain intimate human relationships, and a right to associate for the purpose of engaging in those activities protected by the First Amendment—speech, assembly, petition for the redress of grievances, and the exercise of religion.'" *American Lithuanian Naturalization Club, Athol, Mass., Inc. v. Board of Health of Athol*, 446 Mass. 310, 324 (2006) (quoting *Concord Rod & Gun Club, Inc. v. Massachusetts Comm'n Against Discrimination*, 402 Mass. 716, 721 (1988)). The regulations at issue here, however, do not implicate any of these protected rights, because they do not prevent plaintiffs from associating with one another for the purpose of engaging in protected First Amendment activity.

Importantly, any patients' rights with respect to marijuana, which is otherwise legally prohibited, *see* G.L. c. 94C, § 32C, derive solely from the Act and the implementing regulations, not from any constitutional source. *See Commonwealth v. Leis*, 355 Mass. 189, 195 (1969) (ruling that there is no constitutional or similarly-fundamental right to use marijuana). Moreover, the DPH regulations' restrictions on qualifying patients' employment of and payment to personal caregivers does not prevent their association to engage in activities actually protected by the First Amendment, such as gathering to engage in speech or to petition the government to change the laws governing medical marijuana. *See Concord Rod & Gun Club, Inc.*, 402 Mass. at 721 (smoking ban in private club "does not infringe the members' rights to maintain relationships with each other or to engage in First Amendment activities"); *Caswell v. Licensing Comm'n for Brockton*, 387 Mass. 864, 871-72 (1983) (freedom of association does not provide constitutional right on part of potential patrons to gather at arcade to play video games); *see also Conejo Wellness Center, Inc. v. Agoura Hills*, 154 Cal. Rptr. 3d 850, 872 (Cal. Ct. App. 2013) ("The ordinances [banning marijuana dispensaries] in no way affect the rights of Conejo's members' to associate and discuss medical marijuana cultivation, storage, and use with whomever they please. What the ordinances do is prohibit Conejo, as an entity, from operating as a marijuana dispensary, something to which . . . it has no statutory or other right.").

Nor does "[t]he fact that communication serves as the primary instrument of conducting business" between a qualifying patient and his or her personal caregiver "alter this conclusion." *Wine & Spirits Retailers, Inc. v. Rhode Island*, 418 F.3d 36, 51 (1st Cir. 2005) (holding that statutes that prohibit certain franchise relationships do not infringe upon First Amendment right to associate) (citing *Giboney v. Empire Storage & Ice Co.*, 336 U.S. 490 (1949)). "'The State does not lose its power to regulate commercial activity deemed harmful to the public whenever

speech is a component of that activity.'" *Id.* at 51 (quoting *Ohralik v. Ohio State Bar Ass'n*, 436 U.S. 447, 456 (1978)).[11]

Finally, there is no merit to plaintiffs' additional claim that the regulations' limitation of one qualifying patient per personal caregiver "interferes with and violates their constitutional and statutory right to medicate with a physician's recommendation." Compl. at p. 11. To the extent that plaintiffs by this statement intend to assert a violation of their right to privacy, which incorporates certain aspects of a patient's relationship with his or her physician,[12] their claims must fail. As noted, plaintiffs' only rights with respect to medical marijuana find their origin in the Act. Otherwise, plaintiffs "have no right, fundamental or otherwise, to become intoxicated by means of the smoking of marihuana." *Leis*, 355 Mass. at 195; *accord Conejo Wellness Center, Inc.*, 154 Cal. Rptr. 3d at 869-72 (municipal ordinance banning medical marijuana dispensary did not implicate constitutional rights); *cf. Ross v. RagingWire Telecomms., Inc*., 174 P.3d 200, 209 (Cal. 2008) (private employer's "decision not to accommodate" employee's medicinal "marijuana use does not implicate plaintiff's right to refuse medical treatment").

In sum, plaintiffs cannot demonstrate any likelihood of success on the merits of their claims, and so their request for injunctive relief should be denied on this basis alone. *Wilson v. Commissioner of Transitional Assistance*, 441 Mass. 846, 858-59 (2004) (finding it unnecessary to address other preliminary injunction factors in light of plaintiff's lack of likelihood of success on the merits); *Student No. 9 v. Board of Educ.*, 440 Mass. 752, 767 (2004) (same).

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[11] *Accord Roberts v. U.S. Jaycees*, 468 U.S. 609, 634-35 (1984) (O'Connor, J., concurring in the judgment) ("[T]he State is free to impose any rational regulation on the commercial transaction itself. The Constitution does not guarantee a right to choose employees, customers, suppliers, or those with whom one engages in simple commercial transactions, without restraint from the State.").

[12] *See, e.g*., G.L. c. 214, § 1B ("A person shall have a right against unreasonable, substantial or serious interference with his privacy."); *Norwood Hosp. v. Munoz*, 409 Mass. 116, 122 (1991) ("This court has recognized the right of a competent individual to refuse medical treatment. We have declared that individuals have a common law right to determine for themselves whether to allow a physical invasion of their bodies.").

B. Both the Balance of Harms and the Public Interest Weigh Heavily Against Entry of a Preliminary Injunction or Other Temporary Relief Here.

Given the low likelihood of plaintiffs prevailing on the merits of their claims, it would be difficult if not impossible for them to establish the quantum of irreparable harm required to demonstrate an entitlement to a preliminary injunction. "What matters as to each party is not the raw amount of irreparable harm the party might conceivably suffer, but rather the risk of such harm *in light of the party's chance of success on the merits*." *Siemens Bldg. Technologies, Inc. v. Division of Capital Asset Mgmt.*, 439 Mass. 759, 762 (2003) (emphasis added) (quoting *Cheney*, 380 Mass. at 617).

Even if this Court were to reach the issue, however, it is clear that the balance of harms weighs in favor of denying a preliminary injunction. Plaintiff Downing will suffer no cognizable harm from continued implementation of the challenged personal caregiver regulations, as he never had *any* right to cultivate or distribute marijuana outside of the limited processes set forth in the Act and its implementing regulations. Moreover, the patient-plaintiffs remain free to cultivate a 60-day supply of marijuana themselves. Act § 13; 105 C.M.R. § 725.035. Or they may select a personal caregiver *other than* Downing—provided the alternative caregiver is not serving in that capacity for any other individual—and that alternative caregiver may cultivate medical marijuana under the hardship exemption until registered dispensaries become operational. *See* 105 C.M.R. §§ 725.020(D), 725.025(A)(3), 725.035; Compl. ¶ 43. Indeed, DPH Regulations permit a qualifying patient to designate up to two personal caregivers in the event that reliance on a single individual to provide medical marijuana proves to be insufficient—though the two designated individuals may cultivate the medical marijuana for the qualifying individual at only one location. 105 C.M.R. § 725.020(E).

The blame for any hardship the patient-plaintiffs may suffer as they attempt to find an alternative personal caregiver may be placed squarely on the shoulders of Downing, who held himself out as eligible to serve as personal caregiver to over 1,000 individuals suffering from debilitating medical conditions, despite the clear directive in DPH's regulations that personal caregivers may not serve in that capacity for more than one individual.[13] Downing, not DPH, is responsible for any harm now claimed by the patient-plaintiffs.

Moreover, the full implementation of the Act and DPH's regulations furthers the public interest in preserving a limited and carefully regulated exception to the general prohibition on marijuana cultivation and distribution under state law. By contrast, the relief sought by plaintiffs here would "adversely affect the public interest" by substantially enlarging the Act's limited exception for hardship cultivation. *Student No. 9*, 440 Mass. at 762. If plaintiffs were to prevail here, Downing would essentially be permitted to operate, under the guise of being a "personal caregiver", a *de facto* dispensary—and a largely unregulated one—cultivating a 60-day supply of medical marijuana for over 1,000 individuals, distributing his product to hundreds (if not thousands) of locations throughout the Commonwealth, with little or no oversight, and getting paid for his services. This arrangement would render the extensive application, certification, inspection, operation, and other requirements for dispensaries essentially meaningless. The dangers posed to the public by this unregulated conduct are real and serious. All of these considerations counsel strongly against the entry of injunctive relief against the DPH's regulations.

[13] DPH's regulations became effective on May 24, 2013. DPH also posted on its website a list of "Frequently Asked Questions" regarding the medical marijuana program, which specifically included the question "What are the requirements for personal caregivers?", and which specifically answered that a personal caregiver may not serve in that capacity for more than one qualifying patient. *See* Commonwealth of Massachusetts, Department of Public Health, FAQ Regarding the Medical Use of Marijuana in Massachusetts at 2 ("FAQs"). The FAQs are attached as **Exhibit D** to this opposition. It was therefore clearly unlawful for Downing to hold himself out as being eligible to serve as a personal caregiver for more than one qualified patient.

CONCLUSION

For the reasons set forth above, this Court should deny plaintiffs' Application for Temporary Restraining Order.

Respectfully submitted,

DEPARTMENT OF PUBLIC HEALTH and CHERYL BARTLETT, as Commissioner of the Department of Public Health,

By their attorneys,

MARTHA COAKLEY
ATTORNEY GENERAL

Timothy J. Casey (BBO No. 650913)
timothy.casey@state.ma.us
Turner H. Smith (BBO No. 684750)
turner.smith@state.ma.us
Assistant Attorneys General
Government Bureau
One Ashburton Place
Boston, Massachusetts 02108-1598
(617) 727-2200

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