COMMONWEALTH OF MASSACHUSETTS

BARNSTABLE, SS.

SUPERIOR COURT CIVIL ACTION NO. BACV2015-00586

AIDS SUPPORT GROUP OF CAPE COD, INC.,
Plaintiff

VS.

TOWN OF BARNSTABLE, et al.,1

Defendants

MEMORANDUM OF DECISION AND ORDER ON PLAINTIFF'S MOTION FOR A PRELIMINARY INJUNCTION

In 2006, our Legislature amended G.L. c. 94C, § 27 to provide that "[h]ypodermic syringes or hypodermic needles for the administration of controlled substances by injection" could only be "sold" in the Commonwealth by pharmacists or certain other licensed professionals. The amendment also limited sale to persons who could prove that they had attained the age of eighteen years. The newly re-written statute, however, did more. It eliminated the remainder of the original statute and thereby lawfully permitted the previously proscribed acts of possessing and delivering hypodermic needles and syringes. Citing this amendment, the plaintiff, AIDS Support Group of Cape Cod, Inc. ("ASGCC"), asserts that it acts lawfully and appropriately when it delivers free needles and syringes to intravenous drug users regardless of age from its program site in a commercial district at 428 South Street, Hyannis, Massachusetts. With the explicit intent of reducing the spread on HIV and Hepatitus C ("HCV") infection among its client community, ASGCC dispenses these needles and syringes in numbers

³ Board of Health of the Town of Barnstable, and Thomas McKean, in his official capacity as Director of Public Health of the Town of Barnstable

² Wholesale druggists licensed under G.L c. 112, manufacturers of or dealers in surgical supplies, and manufacturers of and dealers in embalming supplies.

commensurate with its clients' reported habits and needs. Those needs have increased substantially of late as a result of what all concerned have described as "the present opioid crisis." According to the program's director of prevention and screening services, during its recently concluded fiscal year, ASGCC dispensed needles and syringes at a rate of approximately 10,000 per month.

The Town of Barnstable ("Town") views the matter differently. Pointing to discoveries of discarded hypodermic needles and syringes — sometimes in significant numbers — in public parks, comfort facilities, and areas occupied by numerous homeless persons, the Town has identified what it deems to be "a public health crisis." Several of these discoveries have included evidence tending to show that the source of the discarded materials was the ASGCC program. Consequently, the Town ordered in writing ASGCC to "cease and desist" from "the distribution of any needles/syringes within the Town of Barnstable." As its authority and rationale, the Town claimed in its notice that ASGCC was acting in violation of G.L. c. 94C, § 27 because neither it nor its staff were pharmacists or other licensed professionals statutorily designated. The Town further claimed that ASGCC was acting in violation of G.L c. 111, § 215 because its program was not one of the ten pilot needle-exchanges which the Massachusetts Department of Public Health ("DPH") was authorized to implement and because ASGCC had not obtained local approval, as required of such programs under that statute.

In this setting, ASGCC filed a civil complaint pursuant to G.L. c. 231A, § 1, seeking, inter alia, a declaration by this court that the Town was without lawful authority to issue its cease and desist order. ASGCC also sought a temporary restraining order, under Mass, R.Civ.P.

³ Two written notices were served upon ASGCC. One, issued on September 21 or 22, 2015, was on a pre-printed form completed in handwriting. The other, issued on September 23, 2015, was in letter form.

65(a), enjoining the Town and its agents from enforcing the cease and desist order. After a
hearing in which counsel for the plaintiff and all defendants appeared, the requested temporary
order issued, and a hearing date was set for seven days later to consider whether ASGCC's
motion for preliminary injunctive relief under Mass.R.Civ.P. 65(b) should be granted. The court
thereupon received evidence, including the testimony of ten witnesses and various exhibits, as
well as the parties' legal submissions on November 20 and 23, 2015.

A court may enter a preliminary injunction if, after an abbreviated presentation of the facts and the law, the plaintiff has demonstrated 1) a reasonable likelihood of success on the merits of the claims and 2) a substantial risk of irreparable harm if the injunction does not issue.

Packaging Indus. Group, Inc. v. Cheney, 380 Mass. 609, 617 (1980). Additionally, where one of the parties is a public entity, "the risk of harm to the public interest also may be considered."

GTE Products Corp. v. Stewart, 414 Mass. 721, 723 (1993). If the plaintiff meets its burden, then the court must balance the risk of harm to the plaintiff against any similar risk of irreparable harm that an order granting the injunction would create for the defendant. "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. Only where the balance between these risks cuts in favor of the moving party may a preliminary injunction properly issue." Id. at 617.

ASGCC has demonstrated a reasonable likelihood of prevailing upon its claim. Both statutory prongs of the Town's position have their difficulties.

While G.L. c. 94C, § 27 sets forth various requisites by which hypodermic needles and syringes may be lawfully "sold," ASGCC points out that the section says nothing about possessing such items and dispensing them without sale. Accordingly, it asserts that its free distribution of needles and syringes was intended by the 2006 amendment to be permissible conduct. The court agrees. G.L. c. 94C, § 27 does not in any way prohibit the conduct of the ASGCC program as it has been described in the evidence. See Director of the Division of Milk Control v. Haseotes, 351 Mass. 372, 373 (1966). The court additionally observes that the statute's amendment, St. 2006, § 172, was enacted with the title, "An Act Relative to HIV and Hepatitus C Prevention," the very aim of the ASGCC program. See Commonwealth v. Savage, 31 Mass.App.Ct. 714, 716 n.4 (1991) ("The title of an act is relevant as a guide to legislative intent"). Moreover, the court notes the breadth of the proscriptions eliminated by the subject amendment, St. 2006, § 172, and the new statute's attention to programs facilitating the safe disposal of sharps (i.e. hypodermic needles and syringes) in communities throughout the Commonwealth. The amendment clearly marked a change in the Legislature's approach to intravenous drug users: a shift away from criminal enforcement and toward the promotion of health. This change appears to be entirely consistent with the stated goals and demonstrated activities of ASGCC's program.

The second statute cited in the Town's notice, G.L. c. 111, § 215, provides as follows:

The department of public health is hereby authorized to promulgate rules and regulations for the implementation of not more than ten pilot programs for the exchange of needles in cities and towns within the commonwealth upon nomination by the department. Local approval shall be obtained prior to implementation of each pilot program in any city and town.

Not later than one year after the implementation of each pilot program said department shall report the results of said program and any recommendations by filing the same with the joint legislative committees on health care and public safety. Again, as pointed out by ASGCC, while the statute places limits upon the number of programs which the DPH may implement, it is silent as to whether others may initiate additional programs, which may or may not resemble those envisioned by the DPH. The statute certainly does not express a prohibition against such programs, and this court is disinclined to infer one. The court sees nothing in the language of G.L. c. 111, § 215 which would fairly support such a severe reading, particularly in light of the decriminalization of the possession and delivery of needles and syringes established by G.L. c. 94C, § 27. Accordingly, the court agrees with ASGCC's argument. Moreover, the description of the ASGCC program offered by the DPH's Director of the Bureau of Infectious Diseases, when he testified in this matter, has not been lost upon this court. Rejecting the characterization suggested by counsel for the Town that the program was unauthorized or unapproved, the witness instead described it as "not contracted." The witness also testified concerning the effect of the pilot-program initiative, noting that, though enacted in 1995, Section 215 has led to the implementation of only five DPH-sponsored programs. One of these is operated by ASGCC in Provincetown, Massachusetts.

Mere likelihood of success, however, does not win injunctive relief. The court must further engage in a suitable weighing of the equities, giving due consideration to any risks of harm to the public interest.

ASGCC states that it is one of the first AIDS organizations established in the United States. Founded in 1983 in Provincetown, it opened a second office in Hyannis in 2007. It describes its mission as fostering "health, independence and dignity for people living with HIV/AIDS and viral hepatitis by providing care, support and housing." Its services include "medical case management, peer support, housing, nutritional programs, testing for HIV, HCV and sexually transmitted infections, and programs to reduce the spread of HIV and HCV."

Because these infections are blood-borne, ASGCC has actively reached out to intravenous drug users to engage them in the agency's services. It has done so since 1995 and these services are now provided throughout Barnstable County as well as Martha's Vineyard and Nantucket.

ASGCC asserts without challenge that, in the nation, Massachusetts, and particularly
Barnstable County, the "epidemics of HIV and HCV are a medical and public health crisis."

Experts in the area agree that intravenous drug users are particularly vulnerable to these
infections. The shared use of injection equipment has been identified as "one of the primary
sources of HIV, HCV, and HBV (Hepatitis B) transmission in the United States." Recent
surveys have shown, according to ASGCC, that approximately one-third of all intravenous drug
users between the ages of 18 and 30 years are infected with HCV and that, among older users,
the rate is at 70% to 90%. Barnstable County, it states, currently has the highest rate of HCV
infection among 15-25 year-olds in Massachusetts. Among its clients generally, ASGCC found
that in July, August and September of this year, 70% tested positive for HCV.

ASGCC began its present program at the Hyannis site in 2009. Its new registrations have increased in number over the years: 18 in 2010; 34 in 2011; 34 in 2012; 72 in 2013; and 183 in 2014.

The approach taken by ASGCC with respect to intravenous drug users is one which the agency and its witnesses assert is standard and effective. Known as "harm reduction," the approach is described as "a set of strategies aimed at reducing the negative consequences of substance abuse, including disease transmission and overdose, while encouraging and facilitating entry into substance abuse treatment." A phlebotomy-trained "harm reduction specialist" at the Hyannis facility testified as to how this approach is employed as part of the intake procedure and

regular care for intravenous drug users. The new client's name and date of birth are recorded upon a card which is coded to protect the person's privacy. The new client is then asked about health insurance. If the person is not insured, guidance is offered to assist the person in acquiring such insurance, most commonly MassHealth. Inquiry is then made of the new client concerning the nature and frequency of his or her intravenous drug ingestion. This information is useful in determining the number of needles and syringes to be issued to the client. This information is also maintained by the agency to keep track of consistent and inconsistent behaviors. Particular attention is paid to counselling all clients toward safe practices and away from shared use and reuse of injection equipment. The client is then tested for HIV and HCV. Additionally, clients are counseled in the areas of vein care, available drug-abuse treatment, and the risks of sexual transmission. Clients in need of acute medical care are brought to the nearby Duffy Community Health Center.

The ASGCC program is not a "needle exchange program." It is a "needle access program." It does not sell needles or syringes and never has. It issues them free of charge upon request. The issuance of new needles and syringes is not dependent upon the return of used needles and syringes. However, such return is actively encouraged by the program, and clients are continually counseled about the hazards of public discard. A kiosk for dropping off used injection materials stands in the lobby of the ASGCC office to accommodate safe client returns. Also, individualized sharps containers are issued to clients along with their needles. ASGCC reports that during its most recent fiscal year, it issued 112,604 syringes and received back 115,209, for a rate of return of 102%.

ASGCC also issues other supplies with the intent of helping its clients to protect their health while engaging in intravenous drug use. These supplemental supplies are likely to include tourniquets, sterile water, alcohol wipes, clean cotton, and cookers which are color-coded to help avoid shared or repeated use. Additionally, Narcan (Naloxone), an opioid antagonist used to reverse overdoses, is provided to clients, along with instruction for its appropriate use. ASGCC states that it issued Narcan to 488 persons in its last fiscal year (i.e. July1, 2014 to June 30, 2015) and that 216 overdose reversals were reported. The agency reports 66 overdose reversals in just the first three months of the current fiscal year.

ASGCC sees its mission as crucial in the context of "Massachusetts's growing opioid crisis." It points to studies showing that many younger drug users have transitioned to intravenous abuse from oral oxycodone abuse within the past 1½ years. Experts in the field have concluded that, as a consequence of this rapid transition has been that between 2012 and 2014, there has been a 57% rise in opioid overdose deaths in Massachusetts. In 2014 alone, 1,200 people in Massachusetts died from unintentional opioid overdoses. Fifty-one of those deaths occurred in Barnstable County.

ASGCC has demonstrated that its approach of "harm reduction" has considerable support among public health professionals, particularly those engaged in attempting to control the spread of infectious diseases such as HIV and HCV. Experts agree that the best way to avoid infection through intravenous drug use, of course, is to avoid abusing drugs. Short of that optimum, the goal of the DPH's Bureau of Infectious Diseases, in the words of Kevin Cranston, its director, is for intravenous drug users to use "a sterile syringe every time a person injects." Ease of access is key to achieving this goal in the opinion of Cranston. He further explained that DPH as a matter of policy does not insist that its pilot programs require that a client return a used needle and/or

⁴ Some of these materials, labelled with ASGCC's contact information, have been offered by the Town to demonstrate a connection between ASGCC and at least some of the publicly discarded needles and syringes discovered by the Town.

syringe in order to obtain a new one. DPH also does not insist that its programs require that clients prove their identity or age. "The more needles you distribute, the safer people are," testified Dr. Robert Heimer, Professor of Microbial Diseases at the Yale University School of Public Health and Professor of Pharmacology at the Yale University School of Medicine. He also testified that research has shown that programs providing their clients with "as many syringes as they need" tend to have greater participation and tend to have better rates of return of used equipment. He added that he favors "relaxed" programs with educational components as being more effective at promoting safe practices among the at-large community of intravenous drug users. He observed that, where needles are scarce, there is a greater likelihood of an outbreak of HIV and HCV infections. Dr. Camilla S. Graham of the Division of Infectious Disease at Boston's Beth Israel Deaconess Medical Center stated that there is "conclusive scientific evidence" that programs providing access to clean needles decrease new HIV infections, increase the numbers of injection drug users who are referred to and retained in substance abuse treatment, and uniquely reach and furnish medical care to disenfranchised populations who are at high risk of HIV infection. She also asserted that programs such as that of ASGCC, providing easy access to clean injection equipment, increase the rates of people seeking treatment while not increasing substance abuse.

The cease and desist order issued by the Town was in effect for approximately forty days, 5 and ASGCC complied with the order. Previously, ASGCC had been visited by 20 to 30 intravenous drug users daily. After the order, the rate fell to 2 to 3 per day.

S The Town of its own accord suspended its September 23, 2015 order on November 3, 2015 for one week for the stated purpose of determining whether the parties could resolve their differences. The instant complaint was filed on November 10, 2015.

ASGCC states that the availability of hypodermic needles and syringes provided by pharmacies was an inadequate alternative to its "harm reduction" model during the period of its ceased operation. In the evidence presented, the consensus of opinion supports this position.

Limited supply has been cited as a serious issue for pharmacy-based distribution, with some outlets imposing strict restrictions upon availability. A survey conducted by ASGCC during the cessation revealed that several pharmacies were repeatedly out of stock while one pharmacy chain limited sales to ten needles per person in any one day. Also, traditional pharmacies have been historically viewed as not being "consumer friendly" to the intravenous-drug-using market. Affordability has been a further issue cited, though ASGCC grants that many of its clients are eligible for MassHealth. Of particular significance to the issues here at hand, though, is that none of the area's pharmacies provide receptacles for the safe discard of used needles and syringes and none provide free Narcan to assist their customers in countering overdoses.

Though, as earlier indicated, the court questions the precise statutory basis cited by the Town in its cease and desist notice, the Town is certainly within its historical authority to act promptly, through its board of health, to remove or otherwise interdict "all nuisances, sources of filth, and causes of sickness within its town... which may, in its opinion, be injurious to the public health." G.L. c. 111, § 122... See *Baker v. Boston*, 29 Mass. 184, 12 Pick. 184, 192-193 (1831). And it may act with special dispatch in emergency situations. See G.L. c. 111, § 30; 310 CMR § 11.05. Whether the Town exercised its authority appropriately under the circumstances here presented, however, is a question best left for a more thorough hearing of ASGCC's complaint and the Town's formal response thereto. In the meantime, this court accepts that the Town's attention to what it perceived to be a public health risk posed by the unprotected discard of used hypodermic needles and syringes was prudently grounded.

The Town's foremost concern from these unprotected discards is the risk of infection to members of the public from needle stick injuries. It is an understandable concern. However, even the Director of its Board of Health granted that such risk is "very low." The aforementioned Dr. Heimer, with his experience specializing in infectious diseases and substance abuse, opined that the chances of such transmission was "miniscule." He estimated that the risk of a HCV infection from a needle stick is approximately 1 in 10,000 and that the corresponding risk of an HIV infection is approximately 1 in a million. Of course, infection is not the only consequence of needle stick injuries. This court received and credits testimony that police officers and other town employees are at increased risk of such injuries owing to the nature of their work. That risk is an ever-present stressor upon such employees and their families. Even if found not to be infected, such employees will have undergone arduous testing, suspension of regular activities, and worrisome waiting. Several needle sticks to police over a period of ten years and one recent near miss by a public works employee were reported; however, no evidence of a transmitted infection was presented.

Both sides have responded to this risk. The Town has installed sharps receptacles at four of its five fire stations. According to witnesses, such devices, if sturdy and designed to prevent tampering, have shown themselves to be effective in facilitating the safe disposal of injection materials. ASGCC, in addition to distributing individual sharps containers and maintaining its own disposal kiosk, has also conducted sweeps of its own neighborhood to locate and secure discarded materials. Both sides have also shown a willingness to expand these efforts and to

⁶ The Town offered into evidence a "fact sheet" published by the World Health Organization (updated November, 2015), concerning "waste generated by health-care activities." The document offered that a person experiencing a stick injury from a needle earlier used on an infected patient had a risk of infection of 30% for Hepatitis B, 1.8% for Hepatitis C, and 0.3% for HIV. No evidence was offered concerning the applicability of these figures to random public settings.

coordinate their resources in doing so (e.g. installing secure sharps receptacles in public comfort facilities, increasing public awareness and education). This willingness, to the court's view, shows the most promise, in both focus and scope, to address the Town's foremost concern.

Greater and more immediate are the risks posed by the ASGCC program ceasing its operation. No witness, no exhibit, and no report offered into evidence denied ASGCC's foundational claim that we today face a "crisis" from the combined epidemics of opiate overdose and HIV/HCV transmission. It is upon this foundation that the plaintiff asserts, "ASGCC's work saves lives."

The assertion is apt. Unquestionably, it is the free needles that draw people to ASGCC's door. These aren't just any people. They are extremely vulnerable people. They are men and women, young and old, people from all places and from all stations. They are our brothers and our sisters. They are driven by a disease that has taken away their choices and left them with a need. To fill this need they require needles and syringes. They can obtain these items under reasonably relaxed conditions from ASGCC --- free of charge, clean, and supplied in ample enough quantities to reduce the necessity to share or reuse. And they get some advice, some equipment, and some training to help keep themselves and others safe. And they get a substance to help keep themselves and others alive.

ASGCC's "harm reduction" approach may not be the perfect approach. No witness has claimed that it is. However, the evidence here presented has persuaded this court that, in this place and at this time, it is an effective approach. It "saves lives." Failing to grant ASGCC's requested injunctive relief would quite clearly place lives in jeopardy.

ORDER

For the foregoing reasons, it is hereby <u>ORDERED</u> that the Plaintiff's Motion for a Preliminary Injunction be <u>ALLOWED</u> in that:

- 1.) The defendants, their agents, and employees are preliminarily enjoined and restrained from enforcing the Town of Barnstable's cease and desist orders, issued against the plaintiff and dated September 22, 2105 and September 23, 2015, and from otherwise prohibiting, restricting and interfering with the possession, distribution and exchange of hypodermic needles and syringes at the plaintiff's place of business at 428 South Street, Hyannis, Massachusetts;
- 2.) On at least one occasion every thirty (30) days, a representative of ASCGG and a representative of the Town shall have a face-to-face meeting to discuss issues of mutual concern relating to the ASCGG's possession, distribution and exchange of hypodermic needles and syringes within the town of Barnstable, the topics of said meetings to include at a minimum:
 - Ways in which the parties may combine or coordinate efforts to reduce instances
 of unprotected and public discard of used injection materials;
 - Ways in which the parties may coordinate efforts to reduce the risk of needle stick injury, including public education;

c. The feasibility of developing a set of metrics to measure the strengths and weaknesses of the working hypothesis-known as "harm reduction."

Dated: Deember 1, 2015

Raymond P. Venry, Ir.
Justice of the Superior Court

A true copy, Attest:/

:10

Clerk