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Writing Sample

The following writing sample is an appellate opinion for *IMS Health Inc. v. Ayotte*, 550 F.3d 42 (1st Cir. 2008), *reversing* 490 F. Supp. 2d 163 (D.N.H. 2007), a First Amendment case that considered whether the state may regulate the commercial use of prescription-information data. Rewriting this opinion was the final assignment in the Judicial Opinion Writing class that I took in the Fall 2008 semester. Certain portions of the discussion in this opinion had to be curtailed to adhere to the 3500-word limit. At the time of the assignment, the First Circuit opinion was still pending; students composed their answers based on the district court opinion and the record.

IMS HEALTH INC., et al.,
Plaintiffs–Appellees,

v.

Kelly AYOTTE,
as Attorney General of the State of New Hampshire,
Defendant–Appellant.

No. 06-cv-280-PB.

United States Court of Appeals,
First Circuit.

Decided Dec. 1, 2008.

AMYX, Circuit Judge.

In this appeal we are called upon to decide the constitutionality of a New Hampshire statute regulating the commercial use of prescription-information data. This statute forbids the use or transfer of such data by pharmacies, insurance companies, and other specified entities for certain commercial purposes. N.H. Rev. Stat. Ann. §§ 31:47-f, 318:47-g, 318-B:12(IV) (2006) ("Prescription Confidentiality Act" or "Act"). Defendant–Appellant Ayotte, for the State of New Hampshire, contends that the Prescription Confidentiality Act regulates conduct, not speech, and so raises no constitutional issue. Plaintiffs–Appellees IMS Health, Inc. and Verispan, LLC argue that we should uphold the District Court's ruling that the Act restricts constitutionally protected speech in violation the First Amendment. For the reasons that follow, we reverse.

I. Background

The facts of this case have been well established in the opinion below. We summarize only the most pertinent facts here.

IMS and Verispan ("plaintiffs") purchase prescription data (data) from pharmacies. Collectively, the plaintiffs purchase and analyze data from billions of prescriptions annually. By the time the plaintiffs receive the data, all patient-identifiable information has been removed, but the data retain information about the prescribing health-care providers. After receiving this "patient-deidentified" data, the plaintiffs sort and reorganize the data to correlate prescribers with prescriptions that they have written.[1]

Once the data are sorted and organized, plaintiffs sell the data to pharmaceutical companies. Since the data reveal the prescribing habits of individual health-care providers, pharmaceutical companies can use the data to hone their marketing efforts. The data reveal, for example, those health-care prescribers that tend to prescribe new

[1] As the District Court's opinion notes, the Prescription Confidentiality Act has spurred plaintiffs to "substantially alter[] their business practices." IMS Health, Inc. v. Ayotte, 490 F. Supp. 2d 163 (D.N.H. 2007), 2007 U.S. Dist. LEXIS 31779, **29–30. Described in this opinion and the opinion below are plaintiffs' business practices before the Act took effect.

drugs, those that prescribe drugs made by the particular pharmaceutical company, and those that prescribe drugs made by competitors.

Such information allows pharmaceutical companies to tailor their marketing strategies to individual prescribers in a technique known as "detailing." Since there is a continual flow of data from pharmacies to plaintiffs to pharmaceutical companies, the pharmaceutical companies can also use the data to determine whether particular detailing strategies are effective.

At trial, plaintiffs brought a facial challenge to the Prescription Confidentiality Act. The plaintiffs claimed that by prohibiting the use or transfer of patient-deidentified data, the Act violated the plaintiffs' First Amendment rights. At the end of the trial, the court held that the Act regulated commercial speech but neither directly served the State's interests nor was narrowly tailored to serve those interests. The court declared the Prescription Confidentiality Act unconstitutional and permanently enjoined the State from enforcing it.

II. Analysis

A. Standing

Standing was contested at trial but not fully explored in the opinion below. The State claimed that the plaintiffs lacked standing because they were not subject to prosecution under the Prescription Confidentiality Act. Despite the State's assertions to this effect, the current Attorney General's interpretation is not binding on future Attorneys General. Also, under at least one possible interpretation of the Act, entities that wish to transmit information to (or receive information from) the plaintiffs may be regulated by the Act, thus suffering possible restrictions on their First Amendment rights. *See* Complaint at 20–24, ¶¶ 55–68. Since the First Amendment protects the "communication," the audience has the right to receive as much as the speaker has the right to speak. *Va. State Bd. of Pharmacy v. Va. Citizens Consumer Council, Inc.*, 425 U.S. 748, 756–57 (1976).

When a law imposing restrictions on speech includes vague provisions—such as the term "other similar entities" in the Prescription Confidentiality Act—the "chilling effect" on speech raises "special First Amendment concerns." *Reno v. Am. Civil Liberties Union*, 521 U.S. 844, 872; *see id.* at 871–72 (suggesting that standing is broadly construed in the context of challenges to criminal laws that restrict speech and pose a threat of "discriminatory enforcement"). To the extent that the Prescription Confidentiality Act may infringe on pharmaceutical companies' right to receive information from plaintiffs, plaintiffs have standing to assert the right to transmit the information; likewise, to the extent that the Act may infringe on pharmacies' right to transmit information to plaintiffs, plaintiffs have standing to assert the right to receive the information.

B. Standard of Review

The State argues that in First Amendment cases, we should afford de novo review of both conclusions of law and mixed questions of law and fact. To support this proposition, the State cites two cases: *Hurley v. Irish-Am. Gay, Lesbian & Bisexual Group of Boston*, 515 U.S. 557, 567 (1995), and *Bose Corp. v. Consumers Union of U.S., Inc.*, 466 U.S. 484, 501 (1984). These cases are unpersuasive. Both *Hurley* and *Bose Corp.* were on appeal from trial decisions that held the speech in question to be outside of the First Amendment's protection. The purpose of de novo review in these cases was to make sure that the trial court's judgment "[did] not constitute a forbidden intrusion on the field of free expression." *Hurley*, 515 U.S. at 567–68 (quoting *New York Times Co. v. Sullivan*, 376 U.S. 254, 285 (1964)). The same rationale does not apply here, since the trial court held that the speech was protected.

In opposition to the State, the plaintiffs assert that since First Amendment inquiries involve "fact-dominated" questions, we should provide only "deferential review" for clear error. *In re Polymedica Corp. Secs. Litig.*, 432 F.3d 1, 4–5 (1st Cir. 2005). The plaintiffs oversimplify the matter. Under *In re Polymedica*, "[m]ixed questions of law and fact fall along a degree-of-deference continuum," with de novo review of legal questions at one end and clear-error review of factual questions at the other. *Id.* at 4 (citing *Johnson v. Watts Regulator Co.*, 63 F.3d 1129, 1132 (1st Cir. 1995)). *Johnson* clarifies the standard. When interpreting a regulation, reviewing courts examine the matter de novo; any fact-finding involved in a question of applicability "is reviewed only for clear error." *Johnson*, 63 F.3d at 1132.

Following *Polymedica* and *Johnson*, the Prescription Confidentiality Act is subject to plenary review. The trial court's findings of fact will remain undisturbed in the absence of clear error, but the legal conclusions based on the factual findings are also subject to plenary review. *See id.* (fact-finding on which a "mixed" question is based, but not the resolution of the question, is "reviewed only for clear error").

C. Interpreting the Prescription Confidentiality Act

The Prescription Confidentiality Act is less than a model of statutory clarity. Before considering the constitutionality of the Act, we must first determine its scope and meaning. The relevant part of the statute provides:

> Records relative to prescription information containing patient-identifiable and prescriber-identifiable data shall not be licensed, transferred, used, or sold by any pharmacy benefits manager, insurance company, electronic transmission intermediary, retail, mail order, or Internet pharmacy or other similar entity, for any commercial purpose, except for the limited purposes of pharmacy reimbursement; formulary compliance; care management; utilization review by a health care provider, the patient's insurance provider or the agent of either; health care research; or as otherwise provided by law. Commercial purpose includes, but is not limited to, advertising, marketing, promotion, or any activity that could be used to influence sales or market share of a pharmaceutical product, influence or evaluate the prescribing behavior of an individual

> health care professional, or evaluate the effectiveness of a professional pharmaceutical detailing sales force. . . .

N.H. Rev. Stat. Ann. § 318:47-f (2008) (effective June 30, 2006).

Words used in a statute are given their plain meaning whenever possible. *Caminetti v. United States*, 242 U.S. 470, 485 (1917). If the words' plain meaning would produce a result "demonstrably at odds with the intentions of the [law's] drafters," then the drafters' intent controls. *U.S. v. Ron Pair Enters. Inc.*, 489 U.S. 235, 242 (1989).

1. "Records" within the Act's reach

Construed literally, the statute applies only to "[r]ecords . . . containing patient-identifiable *and* prescriber-identifiable data." *Id.* (emphasis added). The conjunctive "and" requires that both (1) patient-identifiable *and* (2) prescriber-identifiable data be present in a record before the statute operates—so records containing only one of the two kinds of data would fall outside of the statute's reach. This reading of the statute is at odds with the drafters' intent. According to the legislative history, the legislature passed the Prescription Confidentiality Act to protect physician and patient privacy and to reduce health-care costs. A literal reading of the statute would frustrate this intent: records containing patient-identifiable *or* prescriber-identifiable data would be freely usable or transmissible, so long as the records did not contain both kinds of data. Under this reading, the law would protect neither physician nor patient privacy. In order to give effect to the legislature's intent, we must interpret the word "and" disjunctively, so that a record containing either patient-identifiable *or* prescriber-identifiable data is subject to the statute's restrictions.

2. Breadth of the phrase "or other similar entity"

Plaintiffs interpret the phrase "or other similar entity" to refer to any entity similar to the others described in the full preceding list of persons and businesses. This interpretation, at first glance, seems contrary to the canon of *ejusdem generis*, which states that "when a general term follows a specific one, the general term should be understood as a reference to subjects akin" to the specific term. *Norfolk and W. Ry. Co. v. Am. Train Dispatchers Ass'n*, 499 U.S. 117, 129 (1991) (citing *Arcadia v. Ohio Power Co.*, 498 U.S. 73, 84–85 (1990)). The canon does not control if, as here, "the whole context dictates a different conclusion." *Id.* The phrase "or other similar entity" is proximate to the term "retail, mail order, or Internet pharmacy," which suggests that an "other similar entity" refers only to these specifically enumerated pharmacies. However, if that were true, the phrase "retail, mail order, or Internet pharmacy or other similar entity" would be the last term in the list of entities subject to the Prescription Confidentiality Act—yet this term is not itself preceded by the word "or." Enumerated lists in statutes invariably include a conjunction (either "and" or "or") before the final term in the list. The conjunction serves both to clarify the meaning of the list (which answers the question of whether all or only one of the terms in the list must be present for the statute to apply) and to make the sentence grammatically correct. Unless "or other similar entity" is read as an

independent term in the list, the Act's language would be an aberration of statutory drafting, as well as simply ungrammatical. Consequently, the plaintiffs (as well as the pharmaceutical companies with which plaintiffs do business) may be "other similar entit[ies]" within the meaning of the statute.

D. Does the Prescription Confidentiality Act regulate speech?

The Act regulates two classes of behavior: use of data and transmission of data. We consider each in turn.

1. Use of data by pharmaceutical companies or other recipients of data

The Act's restriction on the use of data is not a restriction on speech. The recipients retain the right to receive and transmit data. The prohibition on certain specified uses of the data is just that: a prohibition on the conduct that constitutes the use, not on the speech to which the use of the data may be directed.

Pharmaceutical companies and their detailers use the data as a tool. The tool just happens to be composed of language. Detailers do not communicate plaintiffs' data to the health-care providers; they use the data to hone their marketing techniques. Prohibiting the use of data for honing advertising and marketing places no limits on the content of the detailers' speech.

Any message that the detailers might wish to communicate remains permissible. The detailers may continue to communicate the same messages regardless of the Prescription Confidentiality Act. The only difference under the Act is that the detailers will have to arrive at the decision to communicate a given message on a basis other than plaintiffs' data.

We hold that the restriction on the use of data for statutorily defined commercial purposes is not a restriction of speech, and so does not abridge freedom of speech under the First Amendment.

2. Transmission of data

Disclosure or publication of "information" is a form of speech. *Bartnicki v. Vopper*, 532 U.S. 514, 527 (2001). The data at issue in this case is a form of information; transmission is a form of disclosure or publication. Plaintiffs' data transmissions are speech.

Plaintiffs argue that the data transmissions are non-commercial speech because the transfers do not "propose a commercial transaction" under *Bd. of Trs. of State Univ. of N.Y. v. Fox*, 492 U.S. 469, 473–74 (1989). The State is right to respond that this is an overly narrow view of commercial speech, which has never been explicitly defined. "[E]xpression related solely to the economic interests of the speaker and its audience"

also qualifies as commercial speech. *Cent. Hudson Gas & Elec. Corp. v. Pub. Serv. Comm'n of N.Y.*, 447 U.S. 557, 561 (1980); *see also Pharm. Care Mgmt. Ass'n v. Rowe*, 429 F.3d 294 (1st Cir. 2005) (applying *Central Hudson*). Although the record reveals that there are transmissions of the data related to uses that are not economically motivated, the only transmissions prohibited by the statute, and thus the only transmissions at issue, are to recipients that make commercial use of the data. Because plaintiffs' data transmissions to entities that make commercial use of the data relate solely to both the plaintiffs' and the recipients' economic interests, the data transmissions are commercial speech.

E. First Amendment analysis

1. Determining the appropriate level of scrutiny

Commercial speech is usually reviewed under "intermediate" scrutiny. *Central Hudson*, 447 U.S. at 566. Under the most common form of intermediate scrutiny, a law restricting speech that is not misleading and that concerns lawful activity will be upheld if the law is narrowly tailored to directly advance a substantial governmental interest. *Id.*, *Bd. of Trs. of State Univ. of N.Y. v. Fox*, 492 U.S. 469, 480 (1989). Although this is the most common test, the case law does not mandate any particular standard of review.

Commercial speech is given "a limited measure of protection, commensurate with its subordinate position in the scale of First Amendment values." *Ohralik v. Ohio State Bar Ass'n*, 436 U.S. 447, 456 (1978). This subordinate position "turns on the nature both of the expression and of the governmental interests served by its regulation." *Central Hudson*, 447 U.S. At 563.

It is the "informational function of advertising" that justifies protecting commercial speech, *id.*, because of the general interest in the "free flow of commercial information," *Va. State Bd. of Pharmacy v. Va. Citizens Consumer Council, Inc.*, 425 U.S. 748, 764 (1976). Advertising helps keep the public well informed about the range of products available and the prices at which they are offered. *Id.* at 765. Advertising aids the "numerous private economic decisions" that largely determine the "allocation of our resources," and "[t]o this end, the free flow of commercial information is indispensable." *Id.* Other cases applying intermediate scrutiny to commercial-speech restrictions have echoed this core concern for the public interest. *E.g.*, *Thompson v. W. States Med. Ctr.*, 535 U.S. 357, 366 (2002) (citing *Va. State Bd. of Pharmacy*, 425 U.S. at 765); *Edenfield v. Fane*, 507 U.S. 761, 766 (1993); *Zauderer v. Office of Disciplinary Counsel of Supreme Court of Ohio*, 471 U.S. 626, 628 (1985).

When the commercial speech in question does not serve an informational function of value to the public, the justification for affording the speech First Amendment protection dwindles. *See Cent. Hudson Gas & Elec. Corp. v. Pub. Serv. Comm'n of N.Y.*, 447 U.S. 557, 563 (1980) ("[T]here can be no constitutional objection to the suppression of commercial messages that do not accurately inform the public about lawful activity.") Speech that is "of largely private concern" warrants "only qualified

constitutional protection." *Trans Union Corp v. Fed. Trade Comm'n*, 267 F.3d 1138 (D.C. Cir. 2001).

Given the scant public interest in the commercial speech at issue here—the transmission of plaintiff's data to pharmaceutical companies—the required level of scrutiny is something less than traditional intermediate scrutiny. Also, the Act regulates only a subset of plaintiff's commercial speech, rather than imposing a complete ban, which further diminishes the need for close scrutiny. *Cf. Thompson v. W. States Med. Ctr.*, 535 U.S. 357, 373 (2002) (quoting *Edenfield v. Fane*, 507 U.S. 761, 770 (1993)) (complete ban on advertising and promotion of "compounded drugs" subject to intermediate scrutiny; burden of justification placed on the government). Consequently, we will apply the *Central Hudson* test, yet afford a certain degree of deference to the State on close questions.

2. Application of the *Central Hudson* test

First we consider the nature of the government interest to discern whether it is substantial. *Central Hudson*, 447 U.S. at 566. The State asserts that the Prescription Confidentiality Act furthers the government's interest in protecting prescribers' privacy "by limiting unwarranted intrusions into the decision-making process of prescribing physicians," Def.'s Trial Memorandum at 20, and in reducing health-care costs. Both of these stated goals tend to promote the general welfare of the public, in which the government has a substantial interest. We conclude that the government has asserted a substantial interest.

The next question is whether the Prescription Confidentiality Act directly advances the government's interest. *Central Hudson*, 447 U.S. at 566. Under the usual intermediate-scrutiny standard, as the District Court noted, the government "must demonstrate that the harms it recites are real and that its restrictions will in fact alleviate them to a material degree." *Edenfield*, 507 U.S. at 770–71. However, unlike in *Edenfield*, the law in question is not a complete ban on a form of commercial speech; the Prescription Confidentiality Act bans only commercial speech if the recipient will use the speech for certain statutorily defined commercial purposes. Also, in this case, the harms flow from in-person solicitations, which are "not visible or otherwise open to public scrutiny." *Ohralik v. Ohio State Bar Ass'n*, 436 U.S. 445, 466 (1978). Because it is "difficult or impossible to obtain reliable proof" of the effects of pharmaceutical companies' use of plaintiffs' data to inform their marketing strategies, requiring a detailed showing of the government's alleged harms would render the companies' detailers "virtually immune" to effective regulation. *Id.* Some deference to the State is appropriate.

The legislative history to the Act, as well as the State's brief for this appeal, outlines the connection between the close watch on prescribers by pharmaceutical detailers that plaintiffs' data allows, the resulting pressure that prescribers feel to prescribe the detailers' medications, and the effect that this pressure has on prescribing practices and, ultimately, health-care costs. Various *amici*, in their briefs, elaborate on these harms and

the connection to the commercial speech subject to the Act. *See generally Brief for AARP et al. as Amici Curiae Supporting Defendant–Appellant* Although the connection between the speech and the harms is not certain, neither is it "mere speculation or conjecture." *Edenfield*, 507 U.S. at 770. We conclude that the Prescription Confidentiality Act does directly advance the government's substantial interest.

Finally, we must determine whether the Act is narrowly tailored to further the government's interest. *Bd. of Trs. of State Univ. of N.Y. v. Fox*, 492 U.S. 469, 480. The narrow-tailoring requirement does not mean that the law must be the least-restrictive means of achieving the desired end. *Id.* If the government could achieve its objective by a means other than restricting speech, it must do so. *Thompson v. W. States Med. Ctr.*, 535 U.S. 357, 371 (2002). Whenever possible, the government should "open the channels of communication" rather than close them. *Va. State Bd. of Pharmacy v. Va. Citizens Consumer Council, Inc.*, 425 U.S. 748, 770 (1976).

The plaintiffs suggest that the State could engage in "counter-detailing," thereby providing prescribers with information that the State deems beneficial, but the cost of such a venture is prohibitive to the point of impossibility. Just as important, a counter-detailing program would do nothing to alleviate the pressure on prescribers; it would only add another source of pressure, albeit in a different direction. In this case, restricting speech is the only means of directly addressing the stated harms because "the speech itself . . . causes the very harm that the government seeks to prevent." *Trans Union Corp. v. Fed. Trade Comm'n*, 267 F.3d 1138, 1142 (D.C. Cir. 2001). Transmission of prescriber-identifiable data to pharmaceutical companies, when used for the commercial purposes defined in the Act, compromises prescriber autonomy and tends to result in higher health-care costs. Restricting the speech removes detailers' ability to place the pressure on prescribers that distorts prescribing behavior. For these reasons, and because the Act proscribes no speech other than the speech leading to the stated harms, we conclude that the Prescription Confidentiality Act is sufficiently narrowly tailored.

III. Conclusion

The Prescription Confidentiality Act regulates both conduct and commercial speech. Because the Act's restrictions on commercial speech are narrowly tailored to directly advance a substantial government interest, the Act survives First Amendment scrutiny. Accordingly, the judgment of the District Court is REVERSED.

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