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INJECTING CAUTION: A NEED FOR ENHANCED STATE-LEVEL ENFORCEMENT TACTICS TARGETING THE COSMETIC USE OF LIQUID SILICONE PRODUCTS

*Katherine Cohen Cooper**

INTRODUCTION

Liquid silicone, first developed commercially for the purposes of insulating electrical transformers, gained popularity in the United States during the second half of the twentieth century as a cosmetic injection.¹ Although the United States Food and Drug Administration (“FDA”) has never approved liquid silicone for cosmetic uses, physicians have injected the substance in patients’ breasts, bodies, and faces for cosmetic enhancement since the 1950s.² In more recent years, as record numbers of patients seek out minimally invasive cosmetic procedures such as injectables, illicit liquid silicone injections have been on the rise.³ Often, patients hoping to obtain quick cosmetic results turn to unlicensed professionals to administer liquid silicone injections, or receive injections of adulterated or industrial-grade silicone.⁴ While these cosmetic interventions can be easy to obtain and cost thousands of dollars less than a similar procedure performed by a licensed physician, these conveniences all too frequently come at the expense of patient health and safety.⁵

The following article provides a background of the development of liquid silicone as a tool for cosmetic enhancement, as well as a brief overview of

* J.D., Harvard Law School, 2013; B.A., Duke University, 2007.

1. Philip Hilts, *Strange History of Silicone Held Many Warning Signs*, N.Y. TIMES, Jan. 18, 1992, <http://www.nytimes.com/1992/01/18/us/strange-history-of-silicone-held-many-warning-signs.html?pagewanted=all&src=pm>.

2. Judy Foreman, *Women and Silicone: A History of Risk*, BOS. GLOBE, Jan. 19, 1992, at 1.

3. Amanda Gardner, *Illegal Silicone Buttock Injections Can Be Deadly, Experts Say*, USA TODAY (Oct. 28, 2011, 2:42 PM), <http://usatoday30.usatoday.com/new/health/story/health/story/2011-10-29/illegal-silicone-buttock-injections-can-be-deadly-experts-say/50978858/1>.

4. Angela Esther Kim, “Wine, Cheese and a Dash of Poison in the Forehead:” Exploring the Evolution of the Injectable Filler Industry and the Consequent Implications for Regulatory Action, at 29 (May 19, 2006) (unpublished 3L student course paper, Harvard Law School) (on file with Digital Access to Scholarship at Harvard), *available at*: <http://dash.harvard.edu/bitstream/handle/1/9414576/KimA06.html?sequence=2>.

5. *Id.* at 29-30.

the historical regulatory approach toward controlling cosmetic uses of these products. The article goes on to describe the current legal status of liquid silicone injections, as well as the scope of its current uses. It also examines various legal and regulatory mechanisms that have been offered as means to control illicit uses of liquid silicone injections. Given the barriers towards achieving effective federal regulation and control of illicit liquid silicone injections, as evidenced through descriptions of the current and historical regulatory regimes, this article concludes that state-level regulation and enforcement will be the most practical route for controlling unsafe and illegal cosmetic liquid silicone procedures. As such, this article advocates for a selection of promising state-level legal reforms targeting both physicians and unlicensed individuals that seek to provide patients with injections of liquid silicone.

I. THE DEVELOPMENT OF LIQUID SILICONE INJECTIONS

The scientific term for liquid silicone is dimethylpolysiloxane fluid.⁶ The silicones are a family of chemically related substances comprised of silicon atoms bonded to oxygen and carbon atoms; silicone polymers range in viscosity from fluids to solids.⁷ Although the term “silicone” has become synonymous with cosmetic uses, the substance was first developed for industrial purposes. During World War II, the United States military used liquid silicone to insulate electrical transformers.⁸ Also during this era, however, U.S. troops stationed in Japan began to notice that drums of transformer insulating fluid were being stolen from docks in Japanese harbors. It became evident that this silicone fluid was being injected into the breasts of Asian prostitutes who sought a more Western appearance to cater to the American servicemen.⁹ Silicone breast injections migrated to America in the 1950s when Asians who practiced the procedure immigrated. Initially, silicone breast injections were black market procedures, most commonly administered to women who worked in the entertainment industry.¹⁰ During the 1950s and early 1960s, transformer fluid made by Dow Corning (“Dow”) was the only liquid silicone product on the market;

6. Rhoda S. Narins & Kenneth Beer, *Liquid Injectable Silicone: A Review of Its History, Immunology, Technical Considerations, Complications, and Potential*, 118 *PLASTIC & RECONSTRUCTIVE SURGERY J.* 77S, 78S (2006).

7. R.R. LeVier, M.C. Harrison, R.R. Cook, & T.H. Lane, *What is Silicone?*, 92 *PLASTIC & RECONSTRUCTIVE SURGERY J.* 163 (Jul. 1993); *see also* M. Sharon Webb, *Cleopatra’s Needle: The History and Legacy of Silicone Injections*, 2 (Jan. 1997) (unpublished course paper) (on file with Harvard Law School).

8. Hiltz, *supra*, note 1.

9. *Id.*

10. Foreman, *supra* note 2.

thus, throughout this time period, only this industrial-grade material was used in these cosmetic procedures.¹¹

As time passed, liquid silicone injections became more mainstream. One physician in Las Vegas was quoted in a 1963 Newsweek article claiming to have injected 16,000 doses of silicone into the breasts of over 200 women.¹² As the popularity of silicone injections grew, reports of adverse events associated with these procedures also became more prevalent. For example, clinicians began to note that liquid silicone injected in the breasts tended to migrate to adjacent areas and form irregular subcutaneous masses.¹³ To address this issue, a Beverly Hills physician named Dr. Sakurai popularized a version of the liquid silicone formula that contained inflammatory agents.¹⁴ These new agents produced scarring around the injection area, and when added to the liquid silicone, helped the silicone fluid to remain immobilized in the desired region.¹⁵ Because these adulterants caused separate problems in patients, Dow developed and marketed a medical grade liquid silicone, intended for use in clinical experimentation.¹⁶

In large part, Dow developed medical grade silicone because the company had become aware that physicians were putting liquid silicone to wide use. Capitalizing on the market potential of medical uses for liquid silicone, Dow established a medical products business division in 1962.¹⁷ Along with this new endeavor came oversight from the FDA. As Dow assumed its new role as a medical products company, the company instituted efforts to avoid misuse of medical grade liquid silicone by its customers. Purchasers of its Medical 360 fluid were required to sign an affidavit stating that the material would only be used for lubrication purposes.¹⁸ Despite this effort, however,

11. E. L. WARRICK, FORTY YEARS OF FIRSTS 169 (1990).

12. Paul E. Chasan, *The History of Injectable Silicone Fluids for Soft Tissue Augmentation*, 120 PLASTIC & RECONSTRUCTIVE SURGERY J. 7, 2034, 2035 (Dec. 2007); see also Webb, *supra* note 7, at 11.

13. See, e.g., N. Ben-Hur, D.L. Ballantyne, T.D. Rees, & I. Seidman, *Local and Systemic Effects of Dimethylpolysiloxane Fluid in Mice*, 39 PLASTIC & RECONSTRUCTIVE SURGERY J. 423 (1967).

14. Chasan, *supra* note 12, at 2035.

15. *Is the FDA Protecting Patients from the Dangers of Silicone Breast Implants?: Hearing before the Human Resources and Intergovernmental Relations Subcommittee of the Committee on Government Operations*, 101st Cong. 30 (Dec. 18 1990) (statement of Norman D. Anderson, M.D., Associate Professor of Medicine and Surgery, Johns Hopkins University School of Medicine, and Former Chairman, General and Plastic Surgery Devices Advisory Panel, FDA).

16. F. McDowell, *Complications with Silicone: What Grade of Silicone? How Do We Know it Was Silicone?*, 61 PLASTIC & RECONSTRUCTIVE SURGERY J. 892 (June 1978).

17. DOW CORNING CORP., HIGHLIGHTS FROM THE HISTORY OF DOW CORNING CORPORATION, SILICONE PIONEER, <http://www.dowcorning.com/content/publishedlit/01-4027-01.pdf>.

18. See Webb, *supra* note 7, at 16-18.

the FDA declared Medical 360 fluid to be a new drug in 1964, requiring the substance to adhere to the Food, Drug and Cosmetic Act (“FDCA”) and submit a successful New Drug Application (“NDA”).¹⁹

II. HISTORICAL REGULATION OF MEDICAL-GRADE LIQUID SILICONE

A. FDA Initially Classifies Liquid Silicone as a “Drug”

In response to the FDA’s classification of Medical 360 fluid as a drug, Dow assembled a panel of scientific experts to begin conducting animal studies involving liquid silicone. These experts were quickly convinced of liquid silicone’s safety, and began to test the fluid in human patients.²⁰ The FDA permitted Dow to begin Phase II human subject trials in 1965, but these studies were replete with design flaws.²¹ Having failed to amass sufficient safety and effectiveness data by 1976, Dow withdrew the Medical 360 NDA and deferred its attempt to gain FDA approval for its liquid silicone product. In 1977, Dow submitted an amended protocol for clinical trials of Medical 360 fluid.²² Noting that Dow’s animal studies had been plagued with inconsistencies, the FDA explicitly required that liquid silicone trials only be used for serious facial deformities; cosmetic applications were not allowed as part of these new clinical trial protocols.²³ As a result, responsibility for liquid silicone as a transitional medical device was given to the Bureau of Devices and given a new investigational device exemption number (“IDE”).²⁴

B. Liquid Silicone is Re-Classified as a “Device” But Does Not Receive Pre-Market Approval

As these renewed clinical trials were underway, the 1976 Medical Device Amendments to the FDCA went into effect. These amendments charged the FDA with identifying drugs that should be re-classified as devices; silicone

19. *Id.*

20. F.L. Ashley, S. Braley, & E.G. McNall, *The Current Status of Silicone Injection Therapy*, 51 *SURGICAL CLINICS N. AM.* 501 (1971).

21. *Id.* Particularly troubling, it was found that silicone fluid tended to disappear from the injection site. However, none of the researchers could determine where this silicone had migrated.

22. Chasan, *supra* note 12.

23. *See Promotion of Drugs and Medical Devices for Unapproved uses: Hearing before the H. Comm. of Human Res. and Intergovernmental Relations Subcomm. of the Comm. on Gov’t Operations*, 102nd Cong., (207-208) (June 11, 1991) (Memorandum from Paul F. Tilton to The Record, September 10, 1990).

24. *Id.* at 208.

injections were deemed a device in 1977.²⁵ Subsequently, Dow researchers continued clinical trials of silicone injections in patients with severe deformities as investigational medical device trials.²⁶ In 1988, the FDA ruled that silicone injections should be considered Class III medical devices, requiring that the devices obtain pre-market approval (“PMA”) from the agency.²⁷ As Dow gathered data for the PMA application, the FDA requested an interim report, which the company filed in 1990. The agency deemed the submitted material unsatisfactory, citing the dearth of long-term follow-up with study patients, insufficient pre- and post-treatment lab studies, no objective measures of improvement, and inadequate demonstrations of individual patient results.²⁸ Dow did not correct these deficiencies in its data, nor did it file a formal PMA application or submit further safety and efficacy information. Thus, the IDE that had allowed Dow to continue clinical trials of the Medical 360 device permanently expired in January 1992; the product was subsequently retired from clinical medicine.²⁹

*C. Despite Lack of Pre-Market Approval, FDA Enforcement Against
Cosmetic Silicone Injections Is Weak*

By 1992, the FDA had never approved liquid silicone injections as either a drug or device.³⁰ Nevertheless, silicone fluid was widely used within the United States medical community at this time.³¹ Particularly popular was the use of liquid silicone to cosmetically shape the face.³² While the FDA occasionally issued rulings reflecting its approbation of silicone injections, the agency generally exhibited ambivalence towards regulating liquid silicone.³³ For example, the FDA became aware that Dr. Norman Orentreich, one of the investigators permitted to conduct liquid silicone trials under Dow’s Medical 360 IDE, was injecting silicone fluid into patients for reasons outside the scope of addressing serious facial deformities, as was

25. JUDITH JOHNSON, CONG. RESEARCH SERV., FDA REGULATION OF MEDICAL DEVICES 5 (June 25, 2012).

26. See Webb, *supra* note 7, at 29.

27. *Regulatory History of Breast Implants in the U.S.*, FOOD & DRUG ADMIN., <http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/ImplantsandProsthetics/BreastImplants/ucm064461.htm> (last visited May 12, 2014).

28. See Webb, *supra* note 7, at 30.

29. See *id.* at 31.

30. Webb, *supra* note 7, at 30 (stating that the IDE for silicone injections “became invalid in January, 1992”).

31. Kim, *supra* note 4, at 25.

32. *Id.* at 24.

33. HR. REP. NO. 102-1064, at 3 (1992).

specified in the IDE protocol.³⁴ While the FDA did respond by dropping Orentreich from the roster of approved investigators, he nevertheless continued to maintain “a robust cosmetic practice as a dermatologist in New York City, with appreciative movie stars as patients.”³⁵ In the face of this defiance, the FDA warned Orentreich about his continued cosmetic usage of liquid silicone and called for an injunction in 1985.³⁶ Ultimately, however, Orentreich was permitted to continue his practice, and the injunction recommendation was placed in permanent abeyance.³⁷ As justification for this inaction, the agency noted its reluctance “to single out one physician when illegal use of liquid silicone was widespread,” and further that issues related to the practice of medicine were best addressed at the state level.³⁸ As cosmetic use of liquid silicone became increasingly widespread without firm regulatory guidance from FDA, the Department of Justice stepped in and began filing injunctions on behalf of the agency to prohibit physicians from injecting silicone fluid in patients.³⁹ In the early 1990s, the Department of Justice filed its own injunction against Dr. Orentreich.⁴⁰ By 1992, the FDA had followed suit, entering consent decrees of permanent injunction against several additional physicians.⁴¹

D. States Attempt to Regulate Liquid Silicone in the Face of FDA Inaction

Although the FDA’s efforts to curb illegal silicone injections were limited between 1964 and 1992, many states were more active in combating such activity during this timeframe.⁴² As data in the medical literature and in clinical practice regarding adverse effects of liquid silicone injections began to accumulate, so too did political attention throughout many regions of the country.⁴³ In Nevada, a Las Vegas plastic surgeon alerted the state’s attorney general to the dangers of these procedures and the health risks it caused for the city’s entertainers.⁴⁴ In 1975, Nevada passed a law criminalizing silicone injections.⁴⁵ States such as California soon followed

34. Webb, *supra* note 7, at 32.

35. *Id.* 32-33.

36. *Id.* at 34.

37. *Id.*

38. *Id.* at 33.

39. Press Release, Food and Drug Admin., Physicians to Stop Injecting Silicone for Cosmetic Treatment of Wrinkles (Feb. 28, 1992), available at <http://www3.scienceblog.com/community/older/archives/M/1/fda0893.htm>.

40. Kim, *supra* note 4, at 24.

41. Judith E. Foulke, *Two Doctors Ordered to Stop Silicone Injections*, FDA CONSUMER, Mar. 1993, at 27.

42. Webb, *supra* note 7, at 23-24.

43. *Id.* at 24.

44. Foreman, *supra* note 2.

45. *Id.*

suit, beginning to prosecute doctors for violating these laws.⁴⁶ Medical malpractice suits and criminal cases brought in state courts were also successfully used to punish and hold responsible physicians and other individuals who harmed patients with liquid silicone injections. In *People v. Ellison*, for example, the defendant was convicted of involuntary manslaughter for recklessly injecting silicone into a transgender woman.⁴⁷ The principal factual issue at trial was whether the silicone injection caused the victim's death.⁴⁸ On appeal, the court held that the victim's death was caused by the silicone injection because expert testimony concluded that the cause of death was suffocation resulting from the presence of silicone vacuoles in the victim's lungs.⁴⁹

III. CURRENT LEGAL AND REGULATORY STATUS OF LIQUID SILICONE

A. FDA Approval of Medical Devices Generally

Under Section 513(a) of the FDCA, the FDA determines whether Premarket Approval ("PMA") applications provide a "reasonable assurance of [a device's] safety and effectiveness" by "weighing any probable benefit to health from the use of the device against any probable risk of injury or illness from such use."⁵⁰ To aid in this process, PMA applicants submit valid scientific evidence, including one or more clinical investigations where appropriate, which FDA reviews to determine whether the device will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the labeling of the device.⁵¹ Medical devices can be evaluated using clinical and non-clinical testing methods.⁵² FDA assesses information provided in a PMA application concerning the extent of probable benefits of the device by taking into account factors such as the types of benefits involved, the magnitude of the benefits, the probability of the patient experiencing one or more benefits, and the duration of the effects.⁵³ These benefits are balanced against the

46. NEV. REV. STAT. § 202.248 (1995); CAL. BUS. & PROF. CODE § 2251 (West 1980); see also *Nelson v. Gault*, 125 Cal. App. 3d 623, 639-40 (Cal. Ct. App. 1981) (holding that physician's testimony that he was aware that silicone was considered illegal and that he was arrested for injecting it without a permit was admissible to prove knowledge of the falsity of the representation made to patient that silicone was inert and harmless).

47. *People v. Ellison*, 100 Ill. App. 3d 282, 283 (1981).

48. *Id.*

49. *Id.* at 290.

50. 21 U.S.C. § 360(a)(2)(C) (2010).

51. *Id.*

52. *Id.*

53. *Id.*

probable risks and harms associated with the device, including the severity and rates of harmful events associated with the use of the device, the probability of a harmful event, and the duration of a harmful event.⁵⁴ Additionally, FDA will consider factors such as uncertainty, characterization of the condition, patient tolerance for risk, availability of alternative treatments, and novelty of the technology in conducting a benefit-risk determination.⁵⁵

In the context of FDA approval for cosmetic or anti-aging devices, measuring efficacy and comparing risks and benefits can be complicated.⁵⁶ As an initial matter, “it is unclear what endpoints the [FDA] should require manufacturers to use in order to prove efficacy.”⁵⁷ Additionally, it may be difficult to identify the “symptoms” associated with aging or with cosmetic problems, as well as to determine what qualifies as relief of those “symptoms.”⁵⁸ Nevertheless, FDA does approve many drugs and devices for cosmetic indications, such as nonprescription contact lenses, breast implants, and Botox.⁵⁹ For example, in seeking approval of Botox cosmetic, Allergan, the product’s manufacturer, conducted studies with co-primary efficacy endpoints of the Investigator’s rating of glabellar line severity at maximum frown at Day 30 after injection and the Subject’s Global Assessment of change in appearance in glabellar lines at Day 30 after injection.⁶⁰ By the primary efficacy endpoint day, Day 30, 80% of subjects had achieved a severity score of none or mild at maximum frown by the investigator’s assessment, compared to 3% of placebo treated patients.⁶¹ On the other hand, the most frequently reported adverse events following injection of Botox Cosmetic were relatively minor, including headache,

54. *Id.*

55. See FOOD & DRUG ADMIN., U.S. DEP’T OF HEALTH & HUM. SERVS., GUIDANCE FOR INDUSTRY AND FOOD AND DRUG ADMINISTRATION STAFF: FACTORS TO CONSIDER WHEN MAKING BENEFIT-RISK DETERMINATIONS IN MEDICAL DEVICE PREMARKET APPROVAL AND DE NOVO CLASSIFICATIONS (Mar. 28, 2012), <http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM296379.pdf>.

56. Maxwell J. Mehlman, et al., *Anti-Aging Medicine: Can Consumers be Better Protected?*, 44 GERONTOLOGIST 304, 306 (2004).

57. *Id.*

58. *Id.*

59. *Id.* at 307.

60. FOOD & DRUG ADMIN, U.S. DEP’T OF HEALTH & HUM. SERVS., APPROVAL RECOMMENDATION FOR STN 100300/5000 SUBMITTED BY ALLERGAN, INC. TO USE BOTULINUM TOXIN TYPE A (BOTOX COSMETIC) FOR TREATMENT OF GLABELLAR FACIAL LINES (Apr. 12, 2002), <http://www.fda.gov/downloads/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/TherapeuticBiologicsApplications/ucm088280.pdf> [hereinafter FDA, BOTOX COSMETIC APPROVAL].

61. *Id.*

respiratory infection, flu, and nausea.⁶² Based on an analysis of these results, the FDA approved Botox Cosmetic for the temporary reduction in the appearance of moderate to severe glabellar lines in 2002.⁶³

B. Legal “Off-Label” Uses of Approved Liquid Silicone Products

While liquid silicone has never received FDA approval for cosmetic use, certain liquid silicone products were approved by the agency as medical devices between 1994 and 1997. Section 201(h) of the FDCA defines “device” as follows:

The term “device” . . . means an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is . . . intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or intended to affect the structure or any function of the body of man or other animals, and which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of its primary intended purposes.⁶⁴

Presently two liquid silicone devices have received pre-market approval from the FDA: Adatosil 5000 and Silikon 1000; these devices are approved for the treatment of complicated retinal detachments.⁶⁵ Pursuant to this approved indication, these liquid silicone products are temporarily injected into the eye to hold the retina in place while it heals.⁶⁶ FDA approval of these liquid silicone products has opened the door for the legal administration of liquid silicone injections for cosmetic treatment. This legal but unapproved indication is known as an “off-label use.”⁶⁷

62. *Id.*

63. *Id.*

64. 21 U.S.C. §321(h) (2010). It is important to note that the definition of a medical device includes any article that is “intended to affect the structure or any function of the body.” Therefore, a product intended for cosmetic use and designed to beautify or promote attractiveness can nevertheless be classified as a medical device by the FDA, regardless of whether the device is intended to be used for reconstructive or solely cosmetic purposes.

65. Erin Gilbert, Andrea Hui, & Heidi A. Waldorf, *The Basic Science of Dermal Fillers: Past and Present: Part I: Background and Mechanisms of Action*, 11 J. DRUGS DERMATOLOGY 1064 (2012).

66. *Vitreoretinal Surgery: ADATO Sil-O-Silicone Oil*, BAUSCH & LOMB, <http://www.bausch.com/en/ECP/Our-Products/Vitreoretinal-Surgery/ADATO-Sil-Ol-Silicone-Oil> (last visited Apr. 10, 2013).

67. “Off-label” and Investigational Use of Marketed Drugs, Biologics, and Medical Devices—Information Sheet, FOOD & DRUG ADMIN.,

FDA defines off-label use as use for an “indication, dosage, form, dose regimen, population or other use parameter not mentioned in the approved labeling” of a drug or device.⁶⁸ While off-label use of drugs has long been authorized by the FDA, Congress more recently extended the same endorsement of off-label use to devices when it passed the Food and Drug Administration Modernization Act (“FDAMA”) in 1997.⁶⁹ The FDAMA states that the Act must not “limit or interfere with the authority of a health care practitioner to prescribe or administer any legally marketed device to a patient for any condition or disease within a legitimate health care practitioner-patient relationship.”⁷⁰ FDA maintains this general policy of non-interference with the practice of medicine because “off-label uses or treatment regimens may be important therapeutic options and may even constitute a medically recognized standard of care.”⁷¹ Given the importance of off-label uses in many circumstances, the agency merely constrains off-label use by physicians by admonishing that physicians using “a product for an indication not in the approved labeling . . . have the responsibility to be well informed about the product, to base its use on firm scientific rationale and on sound medical evidence, and to maintain records of the product’s use and effects.”⁷² Essentially, the regulatory status of off-label use and prescribing of drugs and devices represents a conscious choice by Congress to prevent the FDA from regulating the physician-patient relationship, limited only by Congressional recognition of “a patient’s right to seek civil damages in the courts if there should be evidence of malpractice.”⁷³ Given such leeway in the practice of medicine, off-label prescribing by physicians is widespread. An estimated 25% to 60% of all prescriptions are for unapproved uses.⁷⁴

Not only does the FDA endorse off-label uses, but the courts have also affirmed the legitimacy of these activities. The Supreme Court has held that the “ ‘off-label’ usage of medical devices is an accepted and necessary corollary of the FDA’s mission to regulate in this area without directly interfering with the practice of medicine.”⁷⁵ Further, “no court has held that a physician’s deviation from the officially approved labeling . . . is per se

<http://www.fda.gov/regulatoryinformation/guidances/ucm126486.htm> (last visited May 12, 2014).

68. *Drug Maker to Pay \$430 Million Fines, Civil Damages*, FOOD & DRUG ADMIN. (Aug. 2004), http://www.fda.gov/fdac/features/2004/404_wl.html (last visited May 12, 2014).

69. See 21 U.S.C. § 396 (2010).

70. *Id.*

71. “*Off-label*” and *Investigational Use*, *supra* note 67.

72. *Id.*

73. *United States v. Evers*, 453 F. Supp. 1141, 1148 (M.D. Ala. 1978).

74. Kim, *supra* note 4, at 11.

75. *Buckman Co. v. Plaintiff’s Legal Comm.*, 531 U.S. 341, 349 (2001).

negligence.”⁷⁶ While a physician’s discretion to use an approved device for an off-label use is not unlimited, and doctors do not “have sole and absolute discretion in treating their patients,”⁷⁷ the ability for physicians to pursue off-label uses is typically quite broad.

Although physicians may use FDA approved drugs and devices for off-label indications, pharmaceutical manufacturers are prohibited from marketing or promoting these off-label uses.⁷⁸ While the FDA is quite active in the realm of enforcement of off-label promotion, the typical circumstances surrounding cosmetic procedures make the ban on off-label promotion less effective in this particular context.⁷⁹ For example, the FDA does not prohibit non-manufacturers from discussing the alleged benefits of off-label uses of approved drugs and devices, whether or not there is evidence to support the professed benefits, nor does it have jurisdiction to regulate international marketing.⁸⁰ Thus, information about cosmetic uses of drugs and devices approved for other indications are often disseminated via the advertisements of physicians who engage in these off-label cosmetic procedures.⁸¹ Further, information about unapproved cosmetic uses may be available on a manufacturer’s international website or on websites maintained by entities that are unaffiliated with the manufacturer.⁸² In fact, media and the Internet play a large role in the American obsession with cosmetic surgery. When it comes to cosmetic procedures and innovations, news of these treatments tend to “spread through mass marketing. The Internet also spreads news and creates demand through list serves, web sites, chat rooms, and spam.”⁸³ The widespread availability of information regarding off-label cosmetic uses of approved drugs and devices “constructs cosmetic surgery as an option which is not only available to everyone, but which bears the promise of an exalted life.”⁸⁴ With a constant barrage of promotions and promises, the allure of cosmetic procedures becomes too irresistible for some to ignore.

At the same time that the mass media extol off-label uses of drugs and devices for cosmetic purposes, data in the medical literature regarding the safety and efficacy of these off-label procedures is often relatively inconclusive. Specifically, researchers and clinicians have eagerly studied

76. Kim, *supra* note 4, at 11.

77. *Cabiroy v. Scipione*, 767 A.2d 1078, 1083 (Pa. Super. Ct. 2001).

78. Kim, *supra* note 4, at 12.

79. *Id.* at 14.

80. *Id.*

81. *Id.*

82. *Id.* at 35-37.

83. Kim, *supra* note 4, at 7.

84. *Id.*

the effects of liquid silicone in soft tissue alteration.⁸⁵ Research has led to the development of a method of administration known as the microdroplet serial puncture technique, in which small amounts of liquid silicone are inserted into the skin at 2-10 mm intervals.⁸⁶ On the one hand, the American Society for Dermatologic Surgery (“ASDS”), which has issued guidelines regarding an array of injectable fillers, deems liquid injectable silicone administered by the microdroplet serial puncture technique to be a safe and efficacious material for permanent intra- and subdermal implantation within the human body.⁸⁷ Physicians and researchers in this camp maintain that the overall cosmetic benefits of liquid silicone injections, and the fact that it permanently remains in the body once injected, outweigh the risks of migration and immune reaction.⁸⁸ Notably, many clinicians prefer liquid silicone to other popular fillers because it can be permanently implanted underneath the skin, unlike collagen, fat, and Botox.⁸⁹ For example, injectable hyaluronic acid, including products such as Restylane and Juvederm that are FDA-approved for injection of moderate to severe facial wrinkles around the nose and mouth, is only a temporary filler, as the substance is metabolized into carbon dioxide and water and eliminated via the lymphatics and eventually the liver.⁹⁰

Liquid silicone’s permanence can also be the source of its potential for problems, including the risk of drift, as it cannot be removed once injected.⁹¹ Many physicians, however, maintain that the problems that plagued silicone in the past can now be attributed to improper technique or using an adulterated or impure formulation. Using silicone in too great a volume, for example, can cause migration; adulterated formulations can lead to ulcers and redness.⁹² Thus, the clinicians that support the use of liquid silicone injections conclude that any possible issues associated with the permanence of liquid silicone, as compared with other injectables, can be remedied with proper attention to administration technique. These researchers caution that, as with any filler, injection using the wrong amount, wrong material, or by the wrong practitioner could result in adverse outcomes, such as swelling,

85. See Doris Maria Hexsel, Camile Luiza Hexsel, & Vivek Iyengar, *Liquid Injectable Silicone: History, Mechanism of Action, Indications, Technique, and Complications*, 22 SEMINARS CUTANEOUS MED. & SURGERY 107 (Jun. 2003).

86. Kim, *supra* note 4, at 24.

87. Murad Alam, et al., *ASDS Guidelines of Care: Injectable Fillers*, 34 AM. SOC’Y DERMATOLOGICAL SURGERY S115, S138 (June 2008).

88. David M. Duffy, *The Silicone Conundrum: A Battle of Anecdotes*, 28 AM. SOC’Y DERMATOLOGICAL SURGERY 590 (July 2002).

89. Melinda T. Willis, *Silicone Injections Make a Comeback*, ABC NEWS (Sept. 20, 2012), <http://abcnews.go.com/Health/story?id=116825&page=1#.UG2ix64TiW8>.

90. Alam, et al, *supra* note 87, at S129-30.

91. Willis, *supra* note 89.

92. *Id.*

beading, and discoloration.⁹³ Thus, the ASDS notes that “judicious use of [liquid injectable silicone] requires an appreciation of normal facial anatomy and the changes that occur with aging and illness,” and suggests that practitioners who perform liquid silicone injections have completed residency training in a specialty where such information is taught, such as dermatology or plastic surgery.⁹⁴

On the other hand, some clinicians argue that liquid silicone injections should be absolutely contraindicated in certain circumstances, including injection into the breasts or horizontal facial creases, or only approached with an abundance of caution in other scenarios, such as in patients with chronic inflammatory disease or an active infection near the proposed injection site.⁹⁵ Given the controversy surrounding liquid silicone, the American Society for Aesthetic Plastic Surgery (“ASAPS”) states that silicone injections for cosmetic purposes should not be used except in the context of a legitimately approved clinical trial.⁹⁶ A plastic surgeon, in recent media coverage about the increasing use of liquid silicone as a facial filler, stated that liquid silicone appears to do a better job on facial lines as far as plastic surgeons presently know, but noted a dearth of research examining the long-term effects and results of these procedures up to 15 years following injection.⁹⁷ Until more concrete research is obtained, he urged physicians to err on the side of caution and avoid procedures involving liquid silicone.⁹⁸ In the face of these uncertainties, physicians must use their best judgment to determine which FDA approved drugs or devices his or her patient should receive in light of the information contained in the product’s labeling and other available scientific data.⁹⁹

These scientific disagreements remain unsettled, despite the fact that a liquid silicone product known as SilSkin was granted an IDE in the early 2000s by the FDA for clinical study of cosmetic improvement of wrinkles and depressions.¹⁰⁰ SilSkin is the only liquid silicone product that has ever been cleared by the FDA for cosmetic clinical trials.¹⁰¹ Its manufacturer, Richard-James, Inc., was able to convince the FDA to allow clinical trials to proceed in part because it presented the agency with results from autopsies

93. Hexsel, et al., *supra* note 85, at 110.

94. Alam, et al, *supra* note 87, at S139.

95. Narins & Beer, *supra* note 6, at 81S.

96. *Face: Liquid Silicone Injections ASAPS—Position*, AM. SOC’Y OF AESTHETIC PLASTIC SURGERY, <http://www.surgery.org/media/news-releases/face—liquid-silicone-injections—asaps—position> (last visited Apr. 10, 2013).

97. Willis, *supra* note 89.

98. *Id.*

99. Kim, *supra* note 4, at 9.

100. Willis, *supra* note 89.

101. Chasan, *supra* note 12.

of silicone users where material injected years earlier had not drifted.¹⁰² Information available near the time that FDA approved this IDE indicated that the Phase II trials would involve 150 patients, followed for one year while receiving SilSkin injections on one side of the face and collagen on the other.¹⁰³ Despite any original optimism surrounding these trials on the part of the manufacturer and physicians, legal issues with SilSkin's manufacturer have prevented Phase III trials from commencing and producing meaningful results.¹⁰⁴ In addition to these FDA-sanctioned clinical trials, a new round of studies involving the injection of Silikon 1000 into nasolabial folds of HIV patients to treat HIV-related lipoatrophy have emerged.¹⁰⁵ Some physicians and researchers believe that these new trials, because they are more rigorously designed than previous studies, will finally "provide objective information regarding outcomes following the use of standardized small volumes of medical grade silicone."¹⁰⁶

Although it remains a hypothetical question, it is important to consider the implications if the FDA were to approve a liquid silicone product for cosmetic uses. FDA approval can trigger the requirement for manufacturers to engage in various forms of postmarket surveillance. Under Section 522, the FDA may order the manufacturer of a Class II or Class III device to conduct postmarket surveillance if the failure of the device would be "reasonably likely to have serious adverse health consequences" or if it is intended to be implanted in the body for more than one year.¹⁰⁷ Arguably, the possibility of silicone migration in the body after injection under the skin could be reasonably likely to have serious adverse health impacts. Further, as a permanent filler, injected liquid silicone would be implanted in the body for more than one year. Thus, FDA approval of a liquid silicone device could trigger helpful postmarket surveillance activities that would enhance monitoring of cosmetic procedures involving liquid silicone.

FDA regulations define this type of surveillance as "the active, systematic, scientifically valid collection, analysis, and interpretation of data or other information about a marketed device."¹⁰⁸ Mandatory postmarket surveillance stemming from FDA-approval of a cosmetic indication of a liquid silicone device would be a great improvement to the currently weak system of tracking and monitoring liquid silicone injections. Currently, the FDA does not track adverse events associated with cosmetic liquid silicone

102. *Id.*

103. Joan Kron, *Inject at Your Own Risk*, ALLURE MAG., Sept. 2002, http://www.facelift.com/2002_injectatyourownrisk.html.

104. *See* Narins & Beer, *supra* note 6, at 79S.

105. *Id.*

106. *Id.*

107. 21 U.S.C. § 3601 (2010).

108. 21 C.F.R. § 822.3(h) (2011).

injections. The CDC's Morbidity and Mortality Weekly Report ("MMWR"), consisting of data gathered from voluntary reporting by state health departments, contains only three mentions of liquid silicone injections.¹⁰⁹ The report, dating back to 2007, warns of acute renal failure associated with silicone injections performed by unlicensed practitioners.¹¹⁰ Thus, at the very least, approval of a liquid silicone product for cosmetic enhancement would be beneficial in remedying the dearth of available adverse event reporting now available.

C. *Illegal Liquid Silicone Injections*

Between 1997 and 2011, the total number of minimally invasive cosmetic procedures, including injectables, performed in the United States increased by nearly 200%.¹¹¹ As detailed above, some of these cosmetic procedures involving the injection of liquid silicone are legal. This occurs when physicians use approved liquid silicone products for unapproved off-label cosmetic purposes. Unfortunately, however, the instances of illegal cosmetic injections of liquid silicone (or other fluids falsely claimed to be liquid silicone) are becoming increasingly widespread. Illegal liquid silicone injections occur when individuals obtain injections at the hands of unlicensed professionals, or when individuals are given injections of adulterated or industrial-grade liquid silicone products.¹¹² Individuals are primarily drawn to the cosmetic procedure black market by the promise of significant cost savings; while it costs roughly \$5,000—7,000 to receive a buttocks lift or implants at a legal clinic, illegal buttocks injections may cost as little as \$250.¹¹³ While cosmetic surgery bargain shopping may save money upfront, "the price to fix a mistake could cost [these individuals] everything," including their health and their lives.¹¹⁴

So-called "bootleg" liquid silicone is readily available, and may be purchased at local home improvement stores or gas stations. Typically, this

109. CTR. FOR DISEASE CONTROL, *Acute Renal Failure Associated with Cosmetic Soft-Tissue Filler Injections—North Carolina*, MORBIDITY & MORTALITY WKLY. REP. (May 2, 2008), <http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5717al.htm>.

110. *Id.*

111. AM. SOC'Y AESTHETIC PLASTIC SURGERY, 15TH ANNUAL COSMETIC SURGERY NATIONAL DATA BANK STATISTICS 7 (2011), <http://www.surgery.org/sites/default/files/ASAPS-Stats2011.pdf>.

112. Phyllis M. Wallace & Sandra Rasmussen, *Analysis of Adulterated Silicone: Implications for Health Promotion*, 12 INT'L J. TRANSGENDERISM 167, 167 (2010).

113. Cristian Salazar, *Illegal Silicone Injection Use Increases Despite Disfigurement, Fatality Reports*, HUFFINGTON POST (Jan. 10, 2010), http://www.huffingtonpost.com/2010/01/10/illegal-silicone-injectio_n_417877.html.

114. Lizzie Crocker & Caitlin Dickson, *Illegal Butt Injections Are on the Rise and Women Are at Risk*, DAILY BEAST (Oct. 13, 2012), <http://www.thedailybeast.com/articles/2012/10/13/illegal-butt-injections-are-on-the-rise-and-women-are-at-risk.html>.

adulterated liquid silicone is industrial-grade, and is often mixed with various impurities.¹¹⁵ Such impurities may include floor products, sealers, motor oil, and paraffin.¹¹⁶ This adulterated silicone fluid is then injected, often by individuals with no training or experience, into “cheekbones, eyebrow bridge, forehead, chin, lips, breasts, pectoral area, armpits, buttocks, penis, thighs, hands, and hips.”¹¹⁷ When silicone injections are performed in this illicit and clandestine manner, individuals who receive injections are often deprived of the opportunity to receive various screening and assessment evaluations that a licensed healthcare provider would typically conduct. These assessments may include an initial consultation by a physician, blood testing for allergic reactions or contraindications, risk and benefit assessment, patient education, or social and psychological evaluations.¹¹⁸ Further, illicit liquid silicone injections too often involve the injection of excessive volumes of silicone, poor technique on the part of unskilled operators, and unhygienic conditions surrounding the procedure.¹¹⁹ A rash of deaths and injuries related to illicit liquid silicone injections have been highlighted in the media in recent years; frequently death occurs following a silicone pulmonary embolism, in which injected silicone travels through the blood stream to the lungs.¹²⁰

Neither the Centers for Disease Control (“CDC”) or the FDA maintain data regarding injuries or deaths caused by illicit cosmetic injections, nor does the public health literature contain substantive information regarding the health implications of illegal liquid silicone injections.¹²¹ Research regarding silicone injections has been most thorough in the context of the transgender population. While other population subgroups including drag queens, heterosexual women, and gay men currently participate in the illicit market for silicone injections, these injections were first adopted widely in the transgender community.¹²² Ruby Corado, one transgender woman profiled in a recent news article, began injecting liquid silicone into her buttocks, hips, and thighs in the late 1990s.¹²³ During a beauty pageant at her transgender club, a man took the stage to pitch silicone injections he offered at a local hotel. The man claimed he was a nurse in Cuba and worked with plastic surgeons, and Corado became hooked on the

115. Wallace & Rasmussen, *supra* note 112, at 168.

116. Kim, *supra* note 4, at 27.

117. Wallace & Rasmussen, *supra* note 112, at 168.

118. *Id.*

119. *Id.*

120. Tracy Woolrich, *Dying for Beauty? The Dangers of Cosmetic Injections*, EXAMINER (Jan. 11, 2010), <http://www.examiner.com/article/dying-for-beauty-the-dangers-of-cosmetic-injections>.

121. Salazar, *supra* note 113.

122. Wallace & Rasmussen, *supra* note 112, at 171.

123. Crocker & Dickson, *supra* note 114.

procedures. Nearly two decades later, however, Corado told reporters that her “silicone hips have migrated to her thighs and her once-juicy booty is hard and sensitive to the touch. Her immune system is weak, but she knows her symptoms could be much worse.”¹²⁴ Such hotel room procedures have been common in the transgender community, as has the phenomenon of dangerous “pumping parties.”¹²⁵ At a typical pumping party, groups of transgender individuals receive silicone injections from an unlicensed, untrained person using non-medical silicone. These parties may occur at a beauty parlor, at a private home, or even in a warehouse. According to one doctor who specializes in transgender health services, economically disadvantaged and vulnerable transgendered individuals are particularly willing to forego safety costs in the pursuit of beauty because being shapely and beautiful is “a self-esteem builder for people who are feeling rejected by their families and communities.”¹²⁶ Given the fact that illicit liquid silicone injections and pumping parties have been popular within the transgender community for quite some time, some data regarding the prevalence of these practices among transgender individuals has been amassed. Research has found “illicit injection silicone rates among transwomen to be 25% in Washington, DC; 30% in New York City and Chicago; and 33% in Los Angeles.”¹²⁷ Moreover, the National Coalition for LGBT Health has confirmed this startling prevalence, reporting that the injection of industrial silicone is so widespread among transpersons that it is one of 13 high priority health issues affecting the population.¹²⁸

In recent years, however, pumping parties have gained popularity amongst other population subgroups outside of the transgender community. For example, many young, African-American women are now pursuing silicone injections to amplify their curves. As one news article put it: “[h]aving once shied away from and even denounced plastic surgery, black women are embracing it now more than ever.”¹²⁹ Pop culture has fueled the desire for a fuller behind, and society has gone from accepting curves to obsessing over large bottoms.¹³⁰ In fact, in 2011, racial and ethnic minorities received 21% of all cosmetic procedures: Hispanics, 8%; African-Americans, 7%; Asians, 5%; and other non-Caucasians, 1%.¹³¹ In addition to the growing popularity among African-American women, Hispanic women are also increasingly turning to illicit liquid silicone injections.

124. *Id.*

125. Wallace & Rasmussen, *supra* note 112, at 171-72.

126. Kim, *supra* note 4, at 27.

127. Wallace & Rasmussen, *supra* note 112, at 169.

128. *Id.*

129. Crocker & Dickson, *supra* note 114.

130. *See id.*

131. AM. SOC’Y AESTHETIC PLASTIC SURGERY, 2011 STATISTICS, *supra* note 111, at 3.

Indeed, South Florida “has become the nation’s capital of black market beauty treatments.”¹³² Many illegal beauty treatments in this region are offered by immigrant practitioners who live in the state, or by foreign health care practitioners who fly to Florida to treat clients.¹³³ Some have noted that “Miami offers perfect-storm conditions for cosmetic crime, [as] it’s a nexus of vanity, greed, corruption, warm weather, beautiful men and women walking around all the time wearing as little clothing as possible and unsophisticated immigrants trying to compete with them.”¹³⁴ The social fabric of Miami and its large immigrant populations can help foster underground cosmetic procedure providers. Women within these tightly knit immigrant communities may be more likely to trust the recommendations of friends and family who have been treated by various black market practitioners.¹³⁵ For example, one Florida woman named Angelina McCabe used local beauty salons to network and get referrals for her silicone lip injection business. When McCabe was ultimately reported by a victim, it came to light that some clients had contracted herpes from her unsanitary syringes, which were found in her medical bag used and covered with dog hair.¹³⁶

IV. REGULATION OF AND ENFORCEMENT AGAINST ILLICIT LIQUID SILICONE INJECTIONS

Given the increasing prevalence of illicit liquid silicone injections, as well as the significant health risks associated with these procedures, it is critical that both the federal government and state and local governments actively enforce laws and regulations designed to curb such practices. At the federal level, this enforcement jurisdiction rests primarily with the FDA. Although physicians may lawfully use an approved liquid silicone product for an off-label cosmetic use, no person may administer unapproved, adulterated liquid silicone devices in any manner. The 1976 Medical Device Amendments to the FDCA established three regulatory classes for medical devices based on risk and the degree of control necessary to ensure safety and effectiveness. Class III devices are the most stringently regulated, and Section 515 of the FDCA requires all Class III medical devices to obtain an approved PMA.¹³⁷ A Class III device that fails to meet PMA requirements is considered to be

132. Natasha Singer, *Beauty on the Black Market*, N.Y. TIMES, Feb. 16, 2006, http://www.nytimes.com/2006/02/16/fashion/thursdaystyles/16skin.html?pagewanted=all&_r=0.

133. *Id.*

134. *Id.*

135. *Id.*

136. Kim, *supra* note 4, at 29.

137. 21 U.S.C. § 360(e) (2010). *See also* 21 U.S.C. § 360(c) (2010).

adulterated under Section 501(f) of the act and cannot be marketed.¹³⁸ Silikon 1000 and Adatosil 5000, the two FDA-approved silicone oil products, are Class III devices that submitted successful PMA applications to the FDA in 1997 and 1994, respectively.¹³⁹

The FDA continues to regulate medical devices once they are successfully approved for marketing in interstate commerce by controlling the contents of the product's labeling. First, the FDA demands that the label of a medical device must not be false or misleading in any particular.¹⁴⁰ Therefore, if a manufacturer falsely held out a silicone oil product for sale to physicians as Silikon 1000 or Adatosil 5000, the product would be misbranded under the FDCA. Second, a medical device's label must provide adequate directions for use.¹⁴¹ The label must therefore include directions related to the FDA-approved use of Silikon 1000 and Adatosil 5000 for the treatment of retinal detachment. Failure to include these adequate directions for use on a label misbrands the device under the FDCA.¹⁴² Furthermore, any addition to the device's labeling that would suggest that the liquid silicone product was FDA-approved for a cosmetic or other indication would cause the device to be adulterated under the FDCA. This is because Section 501(f)(1)(B) of the Act, requiring pre-market approval for Class III devices, considers claims that exceed the scope of a previously FDA-approved indication to adulterate the device.¹⁴³

"Federal regulation of medical products is grounded in the introduction of devices in interstate commerce for commercial distribution, not use by physicians."¹⁴⁴ In regards to medical devices, "the doctrine implies that a licensed physician may use any legally marketed device for any indication that he or she feels is appropriate."¹⁴⁵ This concept forms the basis for the "practice of medicine" doctrine, which maintains that FDA lacks authority under the FDCA to regulate the patient treatment decisions of licensed

138. 21 U.S.C. § 351(f) (2010); *see also PMA Approvals*, FOOD & DRUG ADMIN. <http://www.fda.gov/medicaldevices/productsandmedicalprocedures/deviceapprovalsandclearances/pmaapprovals/default.htm> (last visited May 12, 2014).

139. AM. SOC'Y FOR DERMATOLOGIC SURGERY, LIQUID INJECTABLE SILICONE (May 2007), <http://www.asds.net/TechnologyReportLiquidInjectableSilicone.aspx>.

140. 21 U.S.C. § 352(a) (2010).

141. 21 U.S.C. § 352(f) (2010).

142. *Id.*

143. 21 U.S.C. § 351(f)(1)(B) (2010); *see also* Gerald Masoudi & Christopher Pruitt, *The Food and Drug Administration v. The First Amendment: A Survey of Recent FDA Enforcement*, 21 HEALTH MATRIX: J. L. & MED. 111, 116 (2011).

144. John J. Smith, *Physician Modification of Legally Marketed Medical Devices: Regulatory Implications Under the Federal Food, Drug, and Cosmetic Act*, 55 FOOD & DRUG L.J. 245, 251 (2000).

145. *Id.*

physicians.¹⁴⁶ Thus, federal regulatory efforts are directed primarily at device marketing by manufacturers, not device use by physicians.¹⁴⁷ It is quite possible, therefore, that a state-licensed physician may enjoy wide latitude in treatment use of a medical device that the physician himself or herself has modified, even if the same modification of an FDA-approved device would be sufficient to trigger 501(f)(1)(B) of the Act where a manufacturer made such changes.¹⁴⁸

Therefore, it falls entirely on the state to appropriately regulate the practice of medicine. The Supreme Court has long recognized that the state's police powers justify their regulation of the practice of medicine and allow the state to license health care professionals.¹⁴⁹ Thus, states maintain statutes that regulate various fields of the medical profession and define the scope of practice in which health practitioners may engage.¹⁵⁰ These statutes typically define the authorized practice of medicine and also define and punish unauthorized practice.¹⁵¹ Generally, the unauthorized practice of medicine occurs in one of two scenarios.¹⁵² First, when a person without a medical license performs activities that fall under the definition of the practice of medicine or holds himself or herself out as a licensee.¹⁵³ Second, when an otherwise licensed practitioner performs activities outside the scope of his or her particular medical field.¹⁵⁴ Beyond state medical board oversight, state law also regulates the practice of medicine through private suits for malpractice.¹⁵⁵ Theoretically, "physicians who practice in a manner that is unsafe or ineffective can face disciplinary action and civil liability. But, in reality, state medical boards infrequently discipline physicians for improper practice."¹⁵⁶ In addition, it has been found that the threat of

146. *Id.*

147. *Id.* at 251-52.

148. *Id.*

149. Lars Noah, *Ambivalent Commitments to Federalism in Controlling the Practice of Medicine*, 53 U. KAN. L. REV. 149, 158-59 (2004).

150. John J. Smith, *Physician Modification of Legally Marketed Medical Devices: Regulatory Implications Under the Federal Food, Drug, and Cosmetic Act*, 55 FOOD & DRUG L.J. 245, 251-52 (2000).

151. Jason Bacigalupi, *A Uniform Approach to the Unlicensed Practice of Medicine* 8 (Apr. 24, 2012) (unpublished article) (on file with UNLICENSED HEALTHCARE TASK FORCE, DIV. OF PUB. & BEHAVIORAL HEALTH, NEV. DEPT. HEALTH & HUMAN. SRVS.) http://health.nv.gov/PDFs/unlicensedMedicalActivity/A_UniformApproachtotheUnlicensedPracticeofMedicine.pdf.

152. *Id.* 7-8

153. *Id.*

154. *Id.*

155. *Id.* at 7.

156. Mehlman, *supra* note 56, at 306.

potential malpractice suits also does not seem to deter the proliferation of questionable medical services.¹⁵⁷

While “state statutory definitions [of the practice of medicine] vary tremendously, most of them include diagnosis, prescribing, and surgical interventions among the central attributes of medical practice.”¹⁵⁸ In Florida, Section 456.065 of Chapter 456 of the Florida Statutes regulates the unlicensed practice of a health care profession.¹⁵⁹ The statute prohibits “the unlicensed practice of a health care profession or the performance or delivery of medical or health care services to patients in this state without a valid, active license to practice that profession, regardless of the means of the performance or delivery of such services.”¹⁶⁰ Penalties for the unlicensed practice of a health care profession in Florida include: (1) Issuance of a cease and desist letter when the Department has probable cause to believe an unlicensed person has violated the statute or that a person has aided and abetted the unlicensed practice of a profession by employing an unlicensed person; (2) An administrative penalty not to exceed \$5,000 per incident; (3) A civil penalty of no less than \$500 and no more than \$5,000 for each offense; and (4) Criminal penalties.¹⁶¹

While the existence of state statutory provisions defining the unlicensed practice of medicine is important, it is critical that these laws be effectively and efficiently enforced in order to deter and punish individuals who seek to perform unlawful cosmetic injections. “Florida has a dedicated investigative arm for unlicensed activity.”¹⁶² The Division of Medical Quality Assurance (“MQA”) regulates 37 types of facilities and 43 health care professions.¹⁶³ The MQA serves a variety of functions, including credentialing licensing applicants, inspecting facilities, and decreasing unlicensed activity.¹⁶⁴ The MQA also maintains a separate unlicensed activity unit (“ULA”); in cooperation with law enforcement and state attorney generals, the ULA seeks to prosecute unlicensed practitioners.¹⁶⁵ In order to identify these bad actors, all complaints are routed centrally through the Florida Department of Health.¹⁶⁶ If, upon preliminary review, the complaint is deemed legally sufficient, it is forwarded to a ULA investigator located in close geographic

157. *Id.*

158. Noah, *supra* note 150, at 162-64. *See also* Bacigalupi, *supra* note 151, at 11-25 (overview of unlicensed practice acts in Florida, California, and Oklahoma).

159. Bacigalupi, *supra* note 151, at 19.

160. FLA. STAT. ANN. § 456.065(1).

161. *See id.*

162. Bacigalupi, *supra* note 151, at 26.

163. *Id.*

164. *Id.*

165. *Id.*

166. *Id.*

proximity to the complaint location.¹⁶⁷ Local ULA investigators undertake activities such as interviewing the complainant and witnesses, gathering documents, and conducting surveillance in order to determine whether or not the allegations contained in the complaint are supported.¹⁶⁸ These ULA investigations are designed to develop the probable cause law enforcement entities require to file criminal charges. Fees contributed by licensees fund the ULA; all licensees must pay a \$5 special fee for both initial licensing and each subsequent renewal.¹⁶⁹ According to the program's fourth quarter 2012 Quarterly Performance Report, 99 complaints were filed with the ULA, 76 investigations were completed, 52 cases were referred to law enforcement, and 16 arrests resulted from ULA investigations.¹⁷⁰

California uses a similar vertical prosecution model to enforce its laws related to the unlicensed practice of medicine.¹⁷¹ First, consumers file a complaint with the Medical Board of California.¹⁷² This complaint is directed to the Board's Central Complaint Unit ("CCU"). Then, a Deputy Attorney General and the Complaint Unit Analyst make a determination regarding whether or not immediate investigation or some other government action is warranted by the complaint.¹⁷³ If an investigation is warranted, the CCU forwards relevant information to the District Office in closest proximity to where the alleged acts of unlicensed practice occurred.¹⁷⁴ At this stage, the case is assigned to an investigator and a Deputy Attorney General.¹⁷⁵ This team will work together on the case until it is either: (1) closed; (2) referred for disciplinary action; or (3) referred for other action, including a criminal prosecution.¹⁷⁶ If a criminal prosecution is sought, the team forwards the case file to a district attorney in the relevant jurisdiction.¹⁷⁷

In addition to unlicensed practice statutes, some states include specific language regarding the administration of cosmetic injections and other cosmetic procedures in laws, regulations, and policies that delineate the scope of practice of various health care professions.¹⁷⁸ In particular, many

167. *Id.*

168. Bacigalupi, *supra* note 151, at 26-27.

169. *Id.* at 25-27.

170. FLA. DEP'T OF HEALTH: DIV. OF MED. QUALITY ASSURANCE, QUARTERLY PERFORMANCE REPORT: FISCAL YEAR 2011-2012 FOURTH QUARTER, <http://doh.state.fl.us/mqa/reports.htm#down9>.

171. Bacigalupi, *supra* note 151, at 29-30

172. *Id.*

173. *Id.*

174. *Id.*

175. *Id.*

176. *Id.*

177. Bacigalupi, *supra* note 151, at 29-30.

178. *Id.*

states have issued guidelines regarding which medical professionals are permitted to inject patients with Botox and other dermal fillers.¹⁷⁹ Although these provisions do not explicitly mention liquid silicone injections, states that have restricted cosmetic injections of dermal fillers in some manner include: Alabama, California, Colorado, Florida, Georgia, Kentucky, Maryland, Mississippi, Missouri, New Jersey, New Mexico, Ohio, Oklahoma, Oregon, Rhode Island, South Carolina, and South Dakota.¹⁸⁰ These laws and policies, however, vary widely from state to state.¹⁸¹ Alabama, New Jersey, and South Carolina, for example, restrict cosmetic injections to licensed physicians.¹⁸² In South Carolina, however, this restriction is merely embodied in a policy issued by the state's Board of Medical Examiners; as such, disciplinary action may be the only likely result of its violation.¹⁸³ The policy, issued during the Board's 2002 board meeting, states that "the revision, destruction, or other structural alteration of human tissue using an injection of drugs is surgery. Botox injections should be performed only by individuals licensed to practice medicine and perform surgical services."¹⁸⁴

Many of the other states listed simply provide guidelines for procedures that must or should be followed when a physician delegates the administration of dermal fillers to nurses, physician's assistants, or other allied health professionals. In Maryland, for example, a cosmetic medical procedure can be delegated to a physician's assistant or to another health care professional licensed under the Maryland code whose licensing board states that such procedure falls within the scope of that licensee's practice.¹⁸⁵ Finally, the status of some state laws and policies in this area are conflicting or confused. In Colorado, for example, a broad regulation provides restrictions and guidance related to delegation of medical aesthetic services such as Botox and other injections,¹⁸⁶ but information available from the state's Board of Barbering and Cosmetology states that "[c]ollagen, silicone,

179. *Id.*

180. *See* AM. ACAD. PHYSICIANS ASSISTANTS, SUMMARY OF STATE LAWS, REGULATIONS, & POLICIES AFFECTING PHYSICIAN ASSISTANT PRACTICE IN THE AREA OF AESTHETICS/PLASTIC SURGERY (Nov. 2011), http://www.aapa.org/uploadedFiles/content/The_PA_Profession/Becoming_a_PA/Resource_Items/PlasticSurgery11-11.pdf.

181. *Id.*

182. *Id.*

183. *Id.*

184. *Id.* at 47; *see also* Adopted Bd. Policy on Botox Injections, S.C. DEPT. OF LABOR, LICENSING, AND REGULATION, BD. OF MED. EXAM'RS (Approved Jul. 28-31, 2002).

185. AM. ACAD. PHYSICIANS ASSISTANTS, *supra* note 180, at 29; *see* MD Code Regs. 10.32.09.04 (2010).

186. *Id.* at 12; 3 COLO. CODE REGS. § 713-30 ("Rule 800"); *see also* AM. ACAD. PHYSICIANS ASSISTANTS, *supra* note 180, at 11-12.

or Botox injections are invasive procedures and may only be performed by licensed physicians.”¹⁸⁷

Relatively few states currently maintain laws specifically banning cosmetic uses of liquid silicone. In California, it is a misdemeanor to knowingly prescribe, dispense, administer, or furnish any liquid silicone substance for the purpose of injection into a human breast or mammary.¹⁸⁸ Notably, the breadth of this statute is restricted in two primary ways: first, this law specifies an intent requirement of “knowledge,” and second, only injection of liquid silicone into the breast or mammary is specifically outlawed. In Nevada, with the exception of use for the treatment of retinal detachment, it is unlawful for a person to inject any liquid silicone substance into the body or to sell any liquid silicone substance for the purpose of injection into the human body. Violation of this provision is a category D felony. This law is much stricter than the California statute. The plain language of the Nevada statute implies that it is unlawful for even a physician to pursue cosmetic injections of liquid silicone as an off-label use.¹⁸⁹ While the California and Nevada statutes are the only state regulations currently in force, Rhode Island has proposed a law that would function in a similar manner to Nevada’s law. The proposed statute states that medical licenses may be denied or revoked if a health professional “[performs, assists, or advises] in the injection of any liquid silicone substance into the human body.”¹⁹⁰ While it is promising that a few state legislatures have focused specifically on the dangers of cosmetic liquid silicone injections, it is simultaneously disheartening that these statutes are in effect in so few jurisdictions.

V. THE WAY FORWARD: THE MOST PROMISING LEGAL TACTICS FOR CONTROLLING LIQUID SILICONE INJECTIONS

The rampant use of liquid silicone in cosmetic procedures, despite an overwhelming lack of scientific data and information demonstrating safety and concerns regarding serious health risks, triggers cause for concern and increased attention to the implications of its widespread use. In addition, the growing prevalence of unlicensed practitioners hawking cheap but unsafe, even lethal, illicit liquid silicone injections provides a reason to focus not only on its used by licensed professionals, but also on the market for liquid silicone in general. This section outlines how the federal government could address these issues, but ultimately explains that federal regulation in this area has traditionally been weak, and will not likely be augmented to cover

187. AM. ACAD. PHYSICIANS ASSISTANTS, *supra* note 180, at 12.

188. CAL. PEN. CODE § 382.7 (2010).

189. NEV. REV. STAT. §202.248 (2013).

190. R.I. GEN. LAWS § 5-37.2-15.(19) (2009).

liquid silicone. Thus, in place of enhanced federal enforcement, this section concludes with state-level regulatory and enforcement tactics aimed at both licensed healthcare professionals and unlicensed practitioners.

A. Federal Enforcement Is Unreliable and Likely to Be Weak or Non-Existent

As discussed in parts II and III *supra*, FDA enforcement against off-label cosmetic uses of liquid silicone has historically been weak. Although FDA has never approved a liquid silicone device for cosmetic uses, the agency does not generally interfere with off-label procedures involving these devices. While it is true that the FDA did enter consent decrees of permanent injunction against physicians such as Dr. Norman Orentreich, who violated liquid silicone IDE protocols in the early 1990s, these federal enforcement efforts were relatively weak.¹⁹¹ Further, these injunctions were instigated because physicians were purposely violating IDE protocols specifying that liquid silicone trials were not to involve cosmetic uses.¹⁹² Thus, there is reason to assume that the FDA would be even more hesitant to pursue action against physicians improperly using a device such as SilSkin in a clinical trial, as that product did receive an IDE for cosmetic testing.

Despite the FDA's acceptance of off-label prescribing of approved drugs, it is theoretically possible that Congress could carve out an exception for liquid silicone. Congress could enact a statute that directs FDA to curtail off-label cosmetic uses of approved liquid silicone by physicians. It is difficult to imagine that this sort of legislation would be politically feasible; the medical community is a powerful constituency in any state, and it typically decries FDA regulation of the practice of medicine.¹⁹³ It could be argued, however, that, when it comes to off-label medical uses of silicone fluid specifically, the informal moral and social controls that serve to protect patients do not always work. Due to a convergence of factors including societal pressure to attain beauty standards, the lucrative nature of the cosmetic surgery and procedures industry, and the still largely unknown

191. Philip Hilts, *Under Pressure Doctors Stops Silicone Injections*, N.Y. TIMES, Feb. 6, 1992.

192. Press Release, Food and Drug Admin., *supra* note 39.

193. See, e.g., Sean W. Develin, *Necessary Oversight or Intrusion into the Practice of Medicine?*, ABA HEALTH ESOURCE (Dec. 2012), http://www.americanbar.org/content/newsletter/publications/aba_health_esource_home/aba_health_law_esource_1212_develin.html (noting that an AMA-headed coalition has warned the FDA that it cannot be the body responsible for regulating laboratory-developed diagnostic tests because it is up to physicians, who have the authority and responsibility for practicing medicine, to evaluate the tools appropriate for their patients. As such, the coalition cautioned that efforts to expand beyond the FDA's existing regulatory scope would engender legal challenges).

long-term safety and efficacy profile of injectable liquid silicone, a stronger regulatory stance is needed for this particular device. Indeed, this sort of action would not be entirely unprecedented. Congress has expressly prohibited all off-label use for one drug, human growth hormone (“HGH”). Section 3303(e)(1) of the FDCA makes it a criminal offense for a physician to distribute HGH for any use other than the FDA-approved labeled use.¹⁹⁴

B. State-Level Solutions Can Produce Immediate Results

As noted above, there are significant barriers standing in the way of effective federal enforcement against off-label cosmetic procedures involving liquid silicone. As such, states should be encouraged to take the lead in regulating the off-label and illicit cosmetic uses of liquid silicone. The following section outlines state-level enforcement tactics geared towards both physicians and unauthorized practitioners that promise to be more immediately feasible and practicable than federal solutions.

1. State-Level Enforcement Tactics Targeting Physicians and the Healthcare Community

One of the most promising avenues for state-level efforts to reduce the number of dangerous cosmetic procedures involving liquid silicone performed is encouraging state medical boards to revisit and amend their practice of medicine and scope of practice laws. While the unlicensed practice of medicine tends to attract more negative publicity and media attention, the fact that nearly all U.S. jurisdictions permit any physician with a medical degree and license to perform cosmetic procedures, regardless of his or her level of formal or specialized training in any relevant field, should be deeply troubling, as well.¹⁹⁵ Although approximately 80 percent of licensed physicians receive specialty certification from one of 24 boards approved by the American Board of Medical Specialties, a process requiring at least three years of residency in the chosen concentration area and extensive oral and written exams, there are no laws in the United States that require doctors to practice only within the specialty fields in which they were trained.¹⁹⁶ Further, only Texas, California, Louisiana, and Florida require physicians, in their advertising, to be specific about which specialty board certifications they have; elsewhere, the vague accolade, “board-

194. 21 U.S.C. § 333(e)(1) (2010).

195. Britt Cramer, *Puerto Rico Creates Legal Precedent for Regulation of Aesthetic Medicine*, 40 J.L. MED. & ETHICS 418, 418 (2012).

196. Kate Murphy, *Ear Doctors Performing Face-Lifts? It Happens*, N.Y. TIMES, Jan. 31, 2012, at D5, http://www.nytimes.com/2012/01/31/health/non-specialists-expand-into-lucrative-cosmetic-surgery-procedures.html?_r=0.

certified,” suffices.¹⁹⁷ Because doctors do not have to report to any oversight authority that they are practicing outside their specialty, there are no figures indicating exactly how many physicians are doing so. Nevertheless, media reports of patients being seriously injured by cosmetic surgery performed by unqualified doctors abound, indicating that the unregulated nature of cosmetic surgery is cause for concern.¹⁹⁸

Some physicians who aspire to be cosmetic surgeons attend weekend-long continuing medical education courses, where they learn to perform filler injections and liposuction by physicians who themselves are not certified by the American Board of Plastic Surgery.¹⁹⁹ Often, these newly-minted cosmetic surgeons claim certification by Boards that are not endorsed by the American Board of Medical Specialties, and which have lower standards and are far less rigorous.²⁰⁰

It is precisely these issues that spurred Puerto Rico’s Board of Medical Examiners to enact the nation’s first regulation limiting the practice of cosmetic medicine to particular classes of medical specialists in 2005.²⁰¹ The plaintiff who challenged this regulation was a physician with board certification in obstetrics and gynecology that, while practicing, shifted his focus to performing liposuctions and breast implantations almost exclusively.²⁰² The Board had come to recognize that this “plaintiff’s odyssey was not unique,” and noticed that “the majority of professionals that market[ed] their services as ‘aesthetic medicine’ [were], in reality, general physicians that [had] no formal training . . . in the skills that are purportedly offered to the public.”²⁰³ Thus, the Board deemed it the “illegal practice of medicine [when] any person . . . advertises, practices or purports to practice the procedures that fall under the competence of dermatologists or plastic surgeons without possessing the certification in the corresponding specialty.”²⁰⁴ The First Circuit Court of Appeals upheld this regulation in 2011.²⁰⁵ More states should follow the lead of Puerto Rico and limit the

197. *Id.*

198. For example, a 2012 New York Times article told the story of a middle-aged woman who got a face-lift and tummy tuck from a board-certified doctor in Beverly Hills, only to find out after the surgery (and after suffering adverse outcomes and complications) that her physician’s certification was in otolaryngology, not plastic surgery. The patient noted: “I have an M.B.A. I’m not stupid. But when the doctor has a nice clinic and all those diplomas and certifications on the wall, you think he knows what he’s doing.” *Id.*

199. Murphy, *supra* note 196.

200. *Id.*

201. *Gonzalez-Droz v. Gonzalez-Colon*, 660 F.3d 1, 6 (1st Cir. 2011).

202. *Id.*

203. *Id.* at 7.

204. *Id.*

205. *Id.* at 6.

practice of cosmetic surgery to physicians who have been certified by the American Board of Plastic Surgery or the American Board of Dermatology. These sorts of restrictions may be a necessary step, as there is some evidence that, given how lucrative aesthetic medicine can be for practitioners, doctors who provide these types of services may be less likely to self-regulate in a manner that is sufficiently stringent.²⁰⁶

States can also make enhanced efforts to restrict off-label cosmetic uses of liquid silicone in a manner the FDA cannot or will not, given its commitment to giving physicians a wide berth when it comes to off-label prescribing or use of FDA-approved drugs. As discussed in part IV *supra*, some states have enacted statutes that make it a criminal offense to inject liquid silicone into a person's body. Specifically, the plain language of Nevada's law prohibits all medical uses, cosmetic or otherwise, for liquid silicone products beyond its narrow approved indication for treating retinal detachment.²⁰⁷ More states should consider adopting similar statutes, which would deter cosmetic uses for liquid silicone by licensed physicians and unlicensed practitioners alike.

2. State-Level Enforcement Tactics Targeting Unlicensed Practitioners and Illicit Uses for Liquid Silicone Products

States may be hesitant to interfere with the practice of medicine and a physician's reasoned medical discretion in using approved liquid silicone products for off-label uses. If this is the case, states can focus primarily on eradicating illegal and black market uses of liquid silicone and silicone oil. For example, states can enact laws that regulate the sale of commercial grade silicone, often used in illicit silicone injections by unlicensed practitioners. A parallel area of state legislation that states can use as a model for such laws can be imported from the regulation of the dispensation and distribution of various legal substances that can be used illicitly as inhalants. For example, Ohio Law prohibits dispensing nitrous oxide to any person under the age of 21, or to a person over the age of 21 if the person who dispenses the substance knows or has reason to believe that person over the age of 21 will use the nitrous oxide as an intoxicant.²⁰⁸ The law also requires those who dispense or distribute nitrous oxide cartridges to comply with record-keeping and labeling requirements.²⁰⁹ Anyone who dispenses nitrous oxide must record each transaction on a card, which must include the purchaser's signature and residence address, as well as information stating that the nitrous oxide cartridges are to be used only for purposes of preparing food,

206. Cramer, *supra* note 195, at 420.

207. NEV. REV. STAT. § 202.24 (2013).

208. OHIO REV. CODE §2925.32(B)(1)-(2) (2010).

209. *Id.*

and that inhalation of nitrous oxide can have dangerous health effects.²¹⁰ Further, the law requires each cartridge of nitrous oxide dispensed or distributed within the state to bear the following warning label: “Nitrous oxide cartridges are to be used only for purposes of preparing food. Nitrous oxide cartridges may not be sold to persons under age twenty-one. Do not inhale contents. Misuse can be dangerous to your health.”²¹¹ Similarly, states could apply these types of regulations to liquid silicone products, making it more difficult to purchase these products for illicit uses, and making it easier for the state to track those who do purchase the product.

Another key area for state action targeting illicit uses of liquid silicone products by unlicensed practitioners rests with state attorneys general offices. As discussed in section IV, *supra*, Florida’s ULA has achieved a strong track record in deterring and punishing individuals who offer and conduct dangerous cosmetic procedures within the state.²¹² There are several avenues that can be used to encourage a state attorneys general office to focus enforcement activities in a certain area, such as illicit injections of liquid silicone products. First, licensed practitioner groups, such as state medical associations, could lobby the state to take increased steps to root out bad actors from within the industry that provide off-label cosmetic injections of liquid silicone for profits, despite a lack of scientific knowledge regarding the long-term effects and health consequences of these procedures. In this way, the state can serve as enforcement support in an industry’s attempt to police itself. Second, state attorney general offices can be alerted to the need for increased attention to this issue through consumer complaints. Citizens who have been the victim of dangerous cosmetic procedures involving liquid silicone should be encouraged to report their ordeals to the state; awareness campaigns could help decrease the embarrassment or stigma associated with doing so. Finally, because states often obtain their legislative and enforcement priorities from cases or issues on the horizon in other states, and often learn of national issues from contacts at meetings of organizations like the National Association of Attorneys General (“NAAG”), those interested in promoting more widespread enforcement efforts against illicit liquid silicone injections can attempt to spread awareness of the dangers of these procedures by giving seminars at the meetings and conferences of these associations.²¹³ If states do begin to embark on greater enforcement

210. *Id.*

211. *Id.* at § 2925.32(G)(1).

212. *See* FLA. DEP’T OF HEALTH, DIVISION OF MED. QUALITY ASSURANCE, QUARTERLY PERFORMANCE REPORT: FISCAL YEAR 2011-2012 FOURTH QUARTER, http://www.floridahealth.gov/licensing-and-regulation/reports-andpublications/_documents/qmr-4-11-12.pdf.

213. Telephone Interview with Office of the Att’y Gen. of Mass., Pol’y and Gov’t Div. (Apr. 5, 2013).

efforts in this area, it could be helpful for neighboring jurisdictions to band together and create a reporting network or database, which would store data and information related to the results of these various task forces and investigatory efforts. Given enough traction and progress, the information contained in this database could help public health stakeholders build a case for eventual federal regulation or oversight to curb a major nationwide health issue.

VI. CONCLUSION

Although the FDA has historically focused some regulatory scrutiny on the cosmetic uses of liquid silicone products, the scope of such efforts has been limited, and has not resulted in effective deterrence. While the science regarding the safety and long-term effects of cosmetic liquid silicone injections remains inconclusive, and the illicit uses of liquid silicone on vulnerable populations by unlicensed practitioners grows increasingly more prevalent, it is important to remain cautious, and to keep close watch on these procedures. It is critical, therefore, that states take up the federal slack in this area. States can accomplish this by restricting the use and sale of liquid silicone products by physicians and unlicensed practitioners alike, and also by prioritizing enforcement activities on deterring illicit liquid silicone injections, which are arguably the most lethal, and most hidden, practices involving this substance.

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