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Current State of Drug Recycling Programs in the United States

Nicole Briones*

Abstract

Banco Farmacéutico is an Italian non-governmental organization (NGO). It was founded in 2000 by a group of young pharmacists who recognized the need to provide medicine to the underprivileged. Today, Banco Farmacéutico operates in all of Italy with the support of 4,944 pharmacies, +17,000 pharmacists, and 22,000 volunteers. Banco Farmacéutico started its return of unused and unexpired medications program (RUUM) at pharmacies in 2013. This year Banco Farmacéutico hosted its 20th Medicines Collection Day (MCD), collecting 541,175 over-the-counter medicine packs that were delivered to 1,859 charities affiliated with Banco Farmacéutico to distribute to those in need.

The organization seeks to expand its drug recycling program to be able to more effectively deliver necessary medicine to those who are underprivileged. Banco Farmacéutico is interested in the current state of drug recycling programs in the U.S. This paper provides an analysis of the current status of drug recycling program in the U.S. In addition to an overview of the current legal and operations structure of state programs, interviews were conducted with SIRUM co-founder, Kiah Williams; Good Shepherd Pharmacy & RemediChain founder, Phil Baker; and RAMP CEO, Howard Edelstein who provided further insight and recommendations.

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I. OVERVIEW

Drug recycling programs in the U.S. are enacted at the state level. Thirty-eight states have legislation that enable drug recycling programs to be established, but out of those only 21 states have operational programs. Commonly cited reasons why a state does not have an operational program include lack of funding and resources. Since legislation is at the state level, there is variance in the wording of the statutes. Specific recycling provisions dictate who is allowed to donate, who is allowed to receive donations, who is eligible to receive donations, and what kind of medicine is allowed to be donated.

This paper will, first, detail the current legal structure for most drug repository programs. Second, it will evaluate three successful state programs. Third, it will cover current U.S. drug recycling-based organizations: Supporting Initiatives to Redistribute Unused Medicine (SIRUM), RemediChain, Aid for Aides (AFA), and Recycled AIDS Medicine Program (RAMP). Notably, SIRUM is driving the future of recycling-based programs nationwide; they are credited with establishing many of the state recycling programs. The paper will then analyze the aforementioned via a SWOT based analysis as requested. Finally, it will close with broader recommendations for Banco Farmacéutico.

II. INTRODUCTION

Bloomberg reports that Americans spend on average $1,200 per person per year on prescription drugs; this is more than any other country in the world.\textsuperscript{1} See figures 1–6. The total aggregate number is not settled, but multiple sources report about $344 billion dollars is spent on medicine a year with a projected growth to $420 billion in 2023.\textsuperscript{2} The cost of medicine is too high for many Americans to afford; a census found that 1 in 4 Americans do not refill medically necessary prescriptions due to cost.\textsuperscript{3} See figures 7–10. These staggering numbers are in juxtaposition to the estimated yearly $2 billion drugs wasted in nursing homes and other long-term care facilities (reported by the University of Chicago in 2014)\textsuperscript{4} or yearly estimate of ~$3 billion wasted in cancer drugs (reported by researchers at Memorial Sloan Kettering Cancer Center).\textsuperscript{5} In fact, the Environmental Protection Agency (EPA) estimates that 740 tons of drugs are incinerated or otherwise

\textsuperscript{1} Robert Langreth, \textit{Drug Prices}, BLOOMBERG (Feb. 5, 2019), https://perma.cc/LKX3-WMHV.
\textsuperscript{3} We save medicine to save lives, SIRUM, https://perma.cc/29CG-3XN3.

December 2020 3
wasted by nursing homes a year. As a previous California state senator lamented, “Basically, you’ve got folks on one side of the street who have a desperate need and folks on the other side of the street who are tossing the stuff away. Shouldn’t there be a way to connect them?” This dynamic empowered many states to enact drug recycling laws, thus instead of wasting unused medications, the medications can be redistributed to those in need. Drug recycling programs alleviate financial burden associated with medication costs and reduce environmental waste.

### III. BASIC LEGAL STRUCTURE

The decision to take legislative action to enact policies pertaining to medication donation repository programs is in the power of the states. There are 38 states with passed legislation establishing prescription drug repository programs. See figure 11. Out of those states only 21 have operational repository programs. An “operational program” is defined as a state who has participating pharmacies, charitable clinics, or hospitals collecting, and redistributing donated drugs to eligible patients. Currently, 14 states have no law or program. See figure 12.

Repository programs vary in (1) their scope as to who is allowed to donate medications, (2) who is allowed to receive donated medicine, (3) who is eligible to receive donations, and (4) what types of medicine can be donated.

1. **Who is allowed to donate medications:** One of the main concerns in dictating who is allowed to donate medicine is the need to ensure quality and integrity of the drugs donated. As such, many states only allow medications donated within a closed system, thus ensuring proper handling and storage techniques were used. The National Association of Boards of Pharmacy (NABP) defines a closed system as “the delivery to and/or return of prescription medication from a healthcare or other

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8 Lacey Brinegar Paoli, *The Impact of Medication Donation Repositories: A Policy Analysis*, Univ. of Ky. College of Public Health (Apr. 17, 2019), available at https://perma.cc/4WNM-EXH (“Repository programs serve as a central hub for collecting donated, and previously dispensed, medicated and redistributing it to qualified entities. If the program deems the donated medication unstable, then it is also responsible for properly disposing of it.”).
10 Id.
12 *Position Statement on Drug Repository Program* [hereafter ASCO Position Statement], AMERICAN SOCIETY OF CLINICAL ONCOLOGY, available at https://perma.cc/5HX2-WEXM.
13 Paoli, supra note 8, at 15–16.
institutional facility, which is maintained in a controlled environment under a health care practitioner and not the patient.’’ Note, the NABP only endorses the return and reused of medications that have been maintained in a closed system. Of states who allow donations from a closed system, some have further restrictions such as only from long-term care facilities. Alternatively, other states allow for individuals to donate unused and unopened medications.

(2) **Who is allowed to receive donated medicine:** What is considered a qualified repository facility can drastically vary from state to state. For example, some states stipulate only pharmacies who dispensed the medication originally, charitable clinics, board-approved drop-off locations, physician offices, or any healthcare facility complying with regulation can collect donated medications.

(3) **Who is eligible to receive donated medicines:** Eligible recipients of donated medication tend to be individuals who are at or below 200% of the federal poverty level as well as individuals who are uninsured or underinsured.

(4) **What types of medicines can be donated:** Most drug repository programs exclude controlled substances, expired drugs, or any drug whose integrity is questionable. Programs may include over-the-counter drugs as well. Twelve states have cancer drug specific programs. While each state repository programs is unique, programs tend to incorporate the follow state provisions:

A. **Labeling and Packaging:**

- Donations must be in their original tamper-evident, sealed, and unadulterated packaging.
- Medications in single-unit dose packing may be accepted if the single-unit packaging is unopened.

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15 ASCO Position Statement, supra note 12.
16 Paoli, supra note 8, at 15–16.
17 Paoli, supra note 8, at 15.
18 Paoli, supra note 8, at 16.
20 Id.
21 Id.
22 Id.
23 ASCO Position Statement, supra note 12 (detailing all information regarding standard form of state prescriptions repository programs).
B. Donation and Recordkeeping:

- Donation eligibility limited to outpatient setting kept within a closed distribution system.
- Donations must be inspected by a state-licensed pharmacist or healthcare practitioner for compliance with all labeling and packaging requirements.
- All controlled substances and expired medications are excluded from the repository program.

C. Dispensing:

- Dispensing entities must handle medicine in compliance with all state and federal regulation.
- Donated drugs must meet standards set forth by the Boards of Pharmacy and/or Department of Health.
- Donated drugs can only be dispensed to a patient with a valid prescription.

Statute specifics are determined by the individual state. At this time, the Food & Drug Administration (FDA) does not have a formal statement on their position on drug donation recycling programs. Drug recycling programs have formal supported from both National Association of Board of Pharmacy and American Society of Clinical Oncology.

IV. EXAMINATION OF STATE PROGRAMS

Georgia, Iowa, and California are the states I chose for case study examination. These programs are noted in national publications for their respective success.

It is important to detail reasons why state programs either fail or do not start. Obstacles include lack of awareness about the programs, no central agency designated to operate it, and no budget to fund the program. There are also logistically hurdles to running the program. For example, many medical centers lack sufficient storage for donated drugs, and the additional personnel to manage

24 Direct statements from the FDA are infrequent in this space. Email from George Wang, Director & Co-Founder of SIRUM to Nicole Briones (Dec. 11, 2020) (on file with author). Note the FDA’s Return of Unused Prescription Drugs to Pharmacy Stock Compliancy Guide (CPG) is from the 1980s, prior to the existence to any drug recycling program. The FDA CPG is specifically about returning medications back to a retail pharmacy, not about donating medicine for charity.

25 ASCO Position Statement, supra note 12.

the medicine because regulation mandates medication to be donated in their original packaging, about 90% of the donated medications arrive in blister cards.\textsuperscript{28} Thus, every pill must be taken out of its pack which is a time consuming process for healthcare providers.\textsuperscript{29} Depending on statutory requirements, an added record-keeping burden can be added onto administration.\textsuperscript{30} While this is not an exhaustive list, these issues have been documented as to why some states have no or limited programs.

A. Georgia

In 1997, Georgia created the first state law allowing for a drug recycling program.\textsuperscript{31} However, despite it being the first known state to have an enacted drug recycling statute, their program is relatively new.\textsuperscript{32} After new legislation, the operation of the repository program today is empowered to the Georgia Department of Health.\textsuperscript{33} According to Kiah Williams, co-founder of SIRUM, Georgia has one of the strongest protective legal regimes when it comes to drug repository system in the United States.\textsuperscript{34} Georgia’s strong laws provide an additional incentive for entities to donate and invest in networks. Georgia allows donations from any individual or entity, so long as the medication is in its unopened original packaging and not expired.\textsuperscript{35} Georgia also allows donation of prescription and over-the-counter drugs.\textsuperscript{36} The state currently authorizes five entities to participate in the Donated Drug Repository Program: Alliance Community Pharmacy (antiretroviral medications only), Crossroads Pharmacy (serving patients of a Clinic), PIHC Pharmacy (antiretroviral medications only), Charitable Returns (reverse distributor participants), and Good Pill Pharmacy.\textsuperscript{37}

Good Pill Pharmacy is notable as it is the first pharmacy to solely dispense donated surplus medications.\textsuperscript{38} See figures 13–14. Good Pill Pharmacy has redistributed $5 million dollars of medication and is projected to reach $10 million

\textsuperscript{29} Id.
\textsuperscript{30} Id.
\textsuperscript{31} State Prescription Drug Return, Reuse, and Recycling Laws supra note 9.
\textsuperscript{33} Id.
\textsuperscript{36} Id.
\textsuperscript{37} Id.
\textsuperscript{38} See Good Pill, https://perma.cc/HV9Z-UTGH. Good Pill is currently providing 3 months of medications for free for those who are having trouble getting medications because of Covid-19; Paoli, supra note 8, at 18.
by the end of 2020 (dollar quantity based on wholesale medicine list price). The pharmacy is the first and only non-profit pharmacy in Georgia. It is a partner with SIRUM, and was founded in July 2017. The program begun after a concerned citizen in Georgia reached out to SIRUM wanting to bring a drug recycling program to Georgia. SIRUM worked with Representative Sharon Cooper, Chair of the Health and Human Services Committee, who proceeded to assist in House Bill 897 (2016). The Bill, HB897, provided more expansive power and limited liability, so licensed health care facilities such as hospitals, pharmacies, and long-term care facilities could donate unopened-unexpired medicine.

Good Pill Pharmacy is unique in that it does not distinguish between insured and uninsured, rather it seeks to assist patients who are struggling to afford high-cost medications. They offer a plethora of medications more than 400 ranging from medications for chronic illnesses or diseases such as stroke, disabilities, heart disease, high blood pressure, depression, anxiety, along with some antibiotics. The Pharmacy does not distribute controlled substances or opioids. Good Pill Pharmacy only charges an administration fee of $2 to receive most generic medication. One of the key features of Good Pill Pharmacy is the medicine is shipped to the individual receiving the medication. This is significant as studies show “pharmacy deserts” impact many low-income individuals, thus delivery serves to reduce the burden for people to pick-up prescriptions. This pharmacy has gained a lot of traction, within seven months of operation it was providing medication to ~1,000 Georgians, growing at a monthly rate of 40%. The model of Good Pill and its partnership have been an immense success and serves as a possible national model for other states.

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39 NPR Interview supra note 34.
41 Good Pill Pharmacy, GEORGIA SOCIAL IMPACT COLLABORATIVE, https://perma.cc/PW2R-2ZHM.
42 NPR Interview supra note 34.
43 Id.; See House Bill 897 (2016), text available at https://perma.cc/9692-JWBD. Representative Sharon Cooper is also a licensed nurse, so she understood firsthand how crucial medication accessibility is to the overall improvement in one’s health.
44 Id.
45 Id.
46 Andy Miller, Medicine donation program helps many Georgians who can’t afford what they need, GEORGIA HEALTH NEWS (Aug. 7, 2018), https://perma.cc/K9CT-9KTS.
47 Id.
48 Id.
49 NPR Interview supra note 34.
50 NPR Interview supra note 34.
51 Paoli, supra note 8, at 19.
B. Iowa

Iowa’s drug repository program is the leading state-funded model. In fact, other states lobby for drug repository program in their home-state based on its success.52 Iowa’s drug repository program, SafeNetRx, is renowned for its success; it is made possible through a partnership with the Iowa Department of Public Health and the Iowa Collaborative Safety Net Provider Network.53 See figure 15. There is not an up-to-date number, but in 2018 it was reported from 2007-2016 SafeNetRx provided more than 78,000 residents with medication, estimating about $21.5 million in free medication and supplies donated to people in need with more than 230 medical facilities and pharmacies.54 In 2019, it is estimated that the repository program distributed more than $8 million worth of free medication to patients.55 It is estimated that for every $1 used to administer the Iowa Drug Donation Repository generates over $7 in free medications and supplies.56 The program costs the state about $600,000 a year to run.57 The SafeNetRx program works in tandem with the Iowa Department of Public Health to provide medications to qualified Iowans at the cost of a small handling fee or no fee at all.58 The program accepts all types of non-controlled medications—sample, over-the-counter, and cancer.59 The medication must be in their original sealed container or in tamper-evident packaging and not expired.60 As of 2019, SafeNetRx collected donations via placed donation receptacles at nine different cancer centers and by the assistance of 250 partner healthcare centers who acted as repository sites.61 After the medicine is

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52 See Briana Bierschbach, Two students convince lawmakers to create prescription drug repository, MPR NEWS (June 27, 2019), https://perma.cc/4M3S-92TG; Jessica Miles, IN-DEPTH: Iowa repository could be a model for drug donation program in Minnesota, KSTP.COM (May 15, 2019), https://perma.cc/8AXL-3Y4Z. Minnesota is modeled after Iowa’s program, previously Minnesota’s program was narrowly focused on cancer patient medicine, but it was unsuccessful as the laws were too restrictive to gain traction in hospitals; Marshall Allen, More States Hatch Plans to Recycle Drugs Being Wasted in Nursing Homes, PROPUBLICA (Dec. 1, 2017 8:00 AM), https://perma.cc/CJ2V-GD6H.


54 ASCO Position Statement, supra note 12; Mike Maher, Panel says unused drug recycling program 'makes sense' in Vermont, (Dec. 16, 2018), https://perma.cc/7VT6-98MY.

55 Jessica Miles, Iowa repository could be a model for drug donation program in Massachusetts, APHRA (May 17, 2019), https://perma.cc/43FG-57KP.


59 Id.

60 Id.

61 Paoli, supra note 8, at 19–20.
transported to SafeNetRx site. The donated medicines are sorted and organized in a 1,500-square-foot room on tables. The medicines are sorted alphabetically by generic drug name, and a pharmacist comes thru and inspects every tablet. Then the medicines are sorted in small bins to be distributed to patients. Pharmacies do not pay any money to be a part of the program, rather a pharmacist can place an order online where it is filled by a pharmacist at the SafeNetRx repository.

The CEO of SafeNetRx reported the largest demand is for medications for mental/behavioral health as the medicines are expensive and often in a shortage. This may be attributed to SafeNetRx’s Justice Programs: Department of Correction, OC Behavioral Health Medication Voucher (which provides 90 days of behavioral health medication for released inmates with the hope that access may better position the individual for long-term success in their community) and County Jail Program (which provides 90 days of behavioral health medications at no cost for released offenders).

The program has expanded into other areas such as oral surgery medicine, and now as of February 1, 2019, SafeNetRx Pharmacy and National Foundation for Transplants (NFT) partnered together to bring affordable medication to Iowa transplant patients.

C. California

A group of Stanford University medical school students led the movement for California to pass a drug recycling program through their campaign “There Oughta Be a Law” contest sponsored by, then, state Senator Joe Simitian who is currently the Santa Clara County supervisor. California Senate Bill 798 was signed into law by Governor Schwarzenegger in September 2005. The California law authorized a county to establish, by ordinance, a repository and distribution program to provide surplus unused, unopened, tamper-evident packaged

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63 Id.
64 Id.
65 Id.
66 Id.
67 Jessica Miles, IN-DEPTH: Iowa repository could be a model for drug donation program in Minnesota, KSTP.COM (May 15, 2019), https://perma.cc/8AXL-3Y4Z.
70 Edlin, supra note 28.
medication to those in need. In 2008, volunteers in San Jose began to serve county health exclusively out of Santa County’s Public Health Department Pharmacy. In September 2012, with the assistance of SIRUM, a second bill Senate Bill 1329, also authored by Simitian, expanded distribution to include primary care clinics and their pharmacies, to collect and maintain medications. SB 1329 also eliminated the need for county ordinances for drug donations; this was key as regulatory hurdles made it difficult for programs to begin. The 2008 operation eventually expanded into becoming Santa Clara County Better Health Pharmacy; the first non-profit pharmacy in California. Santa Clara Valley Medical Center is the only recipient of unused medication through SIRUM’s program, but donations come from facilities across the state. SIRUM is continuing to assist many state counties to develop their own programs.

D. Other Notable State Accomplishments

- Wyoming program has helped residents fill more than 150,000 prescriptions (worth more than 12.5 million). In 2016, the program provided more than $2.4 million worth of donated prescription medications free of charge on a short-term basis. Since 2008, the program has processed over 88,000 pounds of medications.
- Oklahoma allows the transfer of drugs from nursing home surplus since 2004. From 2004-2018 more than 223,000 prescriptions have been distributing at an estimated savings of $22 million.

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72 Id.
73 Drug donation pharmacies in California, ALTA CENTERS, https://perma.cc/5NGK-R2EU.
74 Edlin, supra note 28.
75 Id.
76 Drug donation pharmacies in California, supra note 73; Lisa Fernandez, Kris Sanchez & LiLi Tan, California’s 1st Drug Donation Pharmacy Opens in San Jose, NBC (Feb. 16, 2016), https://perma.cc/HVA6-8NMH.
77 Edlin, supra note 28.
78 California has the largest population in the U.S.(~39,510,00) as such has an immense opportunity to establish more charity pharmacies to provide for those in need. U.S. Census Bureau, Google (Apr. 3, 2020), https://perma.cc/4S4D-UZ2Y; Telephone Interview with Kiah Williams, Co-Founder, SIRUM, (Oct. 5, 2020).
81 Id.
E. Other State Statistics

| States which allow a person to donate: | 12 |
| States which allow and distribute cancer-related prescription drugs (operational programs): | 7 |
| States that have cancer drug-specific reclamation laws | 12 |
| State Programs Operated by SIRUM: *California, Colorado, Ohio, and Georgia* | 4 |

V. DRUG RECYCLING FOCUSED ORGANIZATIONS

A. Domestic Drug Recycling Programs

1. Supporting Initiatives to Redistribute Unused Medicine (SIRUM)

SIRUM is a 501(c)(3) social venture that connects unutilized surplus drugs from licensed manufacturers, pharmacies, wholesalers, and health facilities to partner pharmacies who distribute the medicine to those in need. See figures 16–18. Founded in 2009, SIRUM is now the largest medicine redistribution program in the United States. How it works is the peer-to-peer platform matches donors and recipients; it is commonly referred to as the “Match.com” for medicine. The organization then manages all backend operations to simplify donating from its partners. At this time, SIRUM predominantly helps organizations donate medicine, but will assist an individual’s donation of unopened medications by providing a shipping label to send to their prescriptions directly to a partner. Because SIRUM and its partners are non-profits, all prescription donations can be a tax deductible. Additionally, organizations are incentivized to donate because then they will not need to pay for incineration costs which can run about $2-3 per pound.

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86 Telephone Interview with Kiah Williams, Co-Founder, SIRUM, (Oct. 5, 2020).
87 *Donate Medication as an Individual*, SIRUM, https://perma.cc/GFC5-RYBW.
88 Id.
89 NPR Interview supra note 34.
The organization is the driving leader and legal expert in the drug recycling industry. They have shipped 19,275 donations through its platform; redistributed $80,083,340 worth of medicine to partners; and donated 886,776 prescriptions to assist those in need.\textsuperscript{90} SIRUM has gained traction and success because the organization is innovative in the way it integrates technology, segments its market, utilizes collected data, and collaborates with its partners.

The first reason why SIRUM is successful is because of its integration of innovative technology. What would be an intensive laborious administrative process is more efficiently done through algorithms. The platform eases the process for users as it enables donor facilities to use the online system or fax to upload their surplus, and recipient clinics to upload “a list of medications to create a ‘formulary’ of their commonly prescribed drugs. Donors are then able to choose from amongst the matching recipients by reviewing factors such as geographic proximity, percent matches, and name recognition.”\textsuperscript{91} In addition to the algorithm optimizing and matching surplus, it forecasts available medicine to ensure a steady supply for a patient.\textsuperscript{92}

Second, SIRUM’s target market for donations is highly diversified. Since donations are never a guarantee, SIRUM mitigates this risk by not depending on a few large suppliers.\textsuperscript{93} As such, their power is in the aggregation of medications through its expansive network.\textsuperscript{94} It targets smaller health facilities and pharmacies who donate about 5-15% of their stock.\textsuperscript{95} These donations, although smaller, correlate to the top 75% of the most requested medications, providing for a more diverse product mix.\textsuperscript{96}

Third, the organization is data driven which assists SIRUM to not only make well-informed decisions but enables them to educate policymakers and the broader public. SIRUM collects and reports the most current information on state recycling programs. It even has a public daily tracker update on its donation statistics along with the corresponding monetary value of the medication available on its website.\textsuperscript{97} The organization has more than a decade worth of information to educate policymakers and the general public.\textsuperscript{98} This is a powerful tool. As my research experience demonstrated the lack of up-to-date information on the current status of state programs. Information and educational proliferation is key

\textsuperscript{90} SIRUM save medicine to save lives [hereafter SIRUM Homepage], SIRUM (last accessed Oct. 17, 2020), https://perma.cc/ZVU5-ALT2.
\textsuperscript{91} FAQ, SIRUM, https://perma.cc/EMW6-VG7L.
\textsuperscript{92} NPR Interview supra note 34.
\textsuperscript{93} NPR Interview supra note 34.
\textsuperscript{94} Id.
\textsuperscript{95} Telephone Interview with Kiah Williams, Co-Founder, SIRUM, (Oct. 5, 2020).
\textsuperscript{96} Id.
\textsuperscript{97} SIRUM Homepage, supra note 90.
\textsuperscript{98} NPR Interview supra note 34.
in order to scale drug recycling programs. SIRUM partnered with National Conference of State Legislatures (NCSL) to update their website page on State Prescription Drug Return, Reuse, and Recycling Laws. The NCSL page is the leading source for aggregated state drug recycling program information.\(^{99}\) Once people know about these programs then the next area of focus is policy, ensuring legislation is passed that empowers drug recycling programs. SIRUM is instrumental in leading policy that establishes a strong foundation to build robust drug recycling programs. In working with policymakers, SIRUM is able to illustrate a data driven narrative that depicts the clear social, environmental, and environmental value of drug recycling programs. Furthermore, SIRUM is a non-profit and non-partisan organization which makes it uniquely positioned to gain support from individuals across all political parties, allowing the organization to keep the focus on helping those in need.

Lastly, SIRUM is innovative in the way it collaborates with its partners. Co-founder, Kiah Williams shared a wealth of knowledge on the topic. She articulated that SIRUM’s process implementation methodology is based on design thinking.\(^{100}\) Design thinking is a human-centric approach to solutions.\(^{101}\) SIRUM spends significant time researching and recording the actions of individuals at pharmacies and healthcare facilities to fully understand the “day in a life” of their current or potential platform users.\(^{102}\) Another exemplary example of design thinking in action is SIRUM’s piloted inventory platform in Georgia.\(^{103}\) This started after a partner location said it would be a useful tool. Many smaller pharmacies still use “visual order” as inventory management which means they look at the shelves to see what gaps of medication they need to order.\(^{104}\) The downfall of this is no data is collected to determine the exact quantity of medicine available, thus making demand-based forecasting difficult. Many SIRUM partner sites do not have sophisticated backend technology as they are smaller scale operations.\(^{105}\) This inventory platform streamlines the partner’s backend operations and enables for data to be aggregated.\(^{106}\) After a successful pilot in Georgia, SIRUM is now beginning to implement it at other locations.\(^{107}\) With time trials and behavior analysis reports, SIRUM is better able to create tools, processes, and programs that are catered to its users.\(^{108}\) Williams emphasized

\(^{99}\) Telephone Interview with Kiah Williams, Co-Founder, SIRUM, (Oct. 5, 2020).

\(^{100}\) See What is Design Thinking?, IDEO, https://perma.cc/6VU2-LPXG.

\(^{101}\) Telephone Interview with Kiah Williams, Co-Founder, SIRUM, (Oct. 5, 2020).

\(^{102}\) Telephone Interview with Kiah Williams, Co-Founder, SIRUM, (Oct. 5, 2020).

\(^{103}\) Id.

\(^{104}\) Id.

\(^{105}\) Id.

\(^{106}\) Id.

\(^{107}\) Telephone Interview with Kiah Williams, Co-Founder, SIRUM, (Oct. 5, 2020).

\(^{108}\) Id.
throughout the interview that in order to have a successful program the focus must be on the “nitty gritty.”

For example, in sending a box for donations to be collected, SIRUM also provides packing tape and a pre-addressed label. The goal is to remove any barrier that would add more work onto already busy workers.

Her philosophy is if you are asking someone to change their behavior, you want to ensure you are not adding more work. Either create a process that is the same amount of work or less.

For example, recordkeeping can become a barrier to adoption as some state statutes may require more records and paperwork for donated medication. The extra administrative burdens can deter an organization from operating a program as it is much easier for them to just dispose of the medicine.

Another synergic value of close partnerships is SIRUM is able to fully understand difficulties its partners are facing. The information can then be channeled into operational and policy discussions.

Another important legal consideration Williams mentioned, in addition to record keeping requirements, is a statute’s provision on liability and jurisdiction. The level of detail of a Good Samaritan law is crucial as issues can arise if the liability protection is not explicit enough. This can have the legal impact of not protecting everyone in the chain system. Being explicit requires all parties who interact with the donation at any point of the supply chain to be explicitly covered by the liability protection. Second, jurisdictional limits are a legal consideration for a state program. As mentioned, part of SIRUM’s strength is in its network aggregation. If a state would like to benefit from network effects, then it must allow its donations to be received or donated interstate as well.

When I asked Williams why she believed drug recycling programs are not more pervasive amongst states she gave two reasons: 1) people do not know about them as there is still a public misconception that drug recycling programs are not legal and 2) an inadequate policy framework can be a disincentive for people to establish a program. Namely, this occurs when the policy overburdens a participant with more work than they would have otherwise.

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109 Id.
110 Id.
111 Id.
112 Telephone Interview with Kiah Williams, Co-Founder, SIRUM, (Oct. 5, 2020).
113 Id.
114 Id.
115 Id.
116 Id.
1. RemediChain

Founded in 2018, RemediChain is a technology startup headquartered in Memphis, Tennessee. RemediChain is a platform that incentivizes the donation and disposal of surplus medication from individuals. Its platform utilizes blockchain technology as the ledger acts as a “single source of truth” for surplus medication, ensuring donated medications are connected with need patients and expired medication are properly disposed. The incorporation of blockchain technology into the drug recycling process enables data to be collected and tracked throughout its entire supply chain lifecycle. Empowered by the Food and Drug Administration Amendments Act of 2007 (FDAAA), there is a legal mandate for prescription drugs packages to have a standard numerical identifiers (SNIs). The SNIs are applied at the point of manufacturing and repacking at the package or pallet-level to facilitate the identification, validation, authentication, and tracing of prescription drugs. This standardization was in response to supply chain threats of counterfeit, diverted, subpotent, substandard, adulterated, misbranded, or expired drugs entering into the distribution channel. The universal standardization of drug serialization allows the RemediChain platform to catalog the SNIs information. The information, if tracked throughout, can be used to verify the donated drug’s history.

Dr. Phil Baker is a licensed pharmacist and the mastermind behind the blockchain integration concept. He is the Founder of RemediChain, Good Shepard Pharmacy. For context, Good Shepard Pharmacy is a 501(c)(3) nonprofit mail order pharmacy. It also has a brick-and-mortar facility. Their model is a monthly membership fee: memberships start at $5 per month and shipping is $10 per package. See figures 19–20. The first week Good Shepard Pharmacy opened in 2015 individuals came into the pharmacy with unopened medication wanting to

117 RemediChain Overview, LINKEDIN, https://www.linkedin.com/company/remedichain/about/.
118 Who We Are, REMEDICHAIN, https://perma.cc/B4LM-ATGN.
119 Id.
120 The blockchain information starts from the manufacturer. Phone Interview with Phil Baker, Founder, Good Shepherd Pharmacy & RemediChain, (Sept. 25, 2020).
123 Id.
124 Id.
125 Phil Baker the idea came to him after reading an article about blockchain. He thought blockchain technology could be advantageously applied to drug recycling programs. From there, he went and bought a “Blockchain for Dummies” book to learn more about its potential application.
donate the medicine to those in need.\textsuperscript{127} Unfortunately, at the time, there was not a reclamation law that allowed individuals to donate drugs. The 2006 Tennessee statute, only allowed drug donations from health facilities and pharmacies.\textsuperscript{128} As Dr. Baker stated in interview with Nashville Public Radio in 2017, “It was probably a weekly occurrence that somebody would call and say my grandfather died, I have all this unopened medicine and in the state of Tennessee I was having to say them ‘I am sorry, I can’t accept donations. You’re just going to have to throw that stuff away.’” This was particularly difficult when individuals were offering expensive anti-nausea medicine for chemotherapy patients.\textsuperscript{129} This is why Baker helped write new legislations allowing individuals as well as nursing homes to donate unexpired-sealed prescriptions.\textsuperscript{130} RemediChain launched its 2020 national campaign for donating prescriptions from individuals: it is called #FlipYourScrip.\textsuperscript{131} The process is simple:

1. Text #FlipYourScrip to 1-833-999-1003 and open the donation form.
2. Send a picture of the medication (if opened front/back side) or of the bottle (if unopened).
3. Enter the name of the drug, dose, and number of pills.
4. Enter your email and zip code - hit submit.
5. If they can connect it with a patient, they’ll schedule a FedEx.
6. If they can’t connect it with a patient, we’ll tell you the nearest take-back/disposal box.
7. Text us a picture of the take-back box to earn a $5 Amazon gift card.\textsuperscript{132}

In the first 100 days of the campaign 485 people texted in ~900 different medication prescriptions. Of those the organization reclaimed 143 oral chemotherapies valued at $1.3 million.\textsuperscript{133} The rest was referred to drug disposal boxes.\textsuperscript{134} Twenty-two chemotherapy drugs were matched with 15 different patients of which 7 patients got more than one fill within the 100 days.\textsuperscript{135}

\textsuperscript{127} Phone Interview with Dr. Phil Baker, Founder, Good Shepherd Pharmacy & RemediChain, (Sept. 25, 2020).
\textsuperscript{130} Id.
\textsuperscript{131} Nick Mulcahy, Text #FlipYourScrip to Easily Donate Unused Drugs, MEDSCAPE (Mar. 10, 2020), https://perma.cc/D2KY-B2AT.
\textsuperscript{132} Homepage, REMEDICHAIN, https://perma.cc/E7CL-WG7H.
\textsuperscript{133} Phone Interview with Dr. Phil Baker, Founder, Good Shepherd Pharmacy & RemediChain, (Sept. 25, 2020).
\textsuperscript{134} Id.
\textsuperscript{135} Id.
Additionally, the organization documented the proper disposal of $500,000 worth of medication that would have otherwise been wasted.\textsuperscript{136}

One of the interesting aspects of this campaign is it is multi-purposed. The main focus is matching donated medications with in-need patients with a specific emphasis for oncology products (i.e. chemotherapies).\textsuperscript{137} The second goal is to collect data on the type and quantity of medications that are being disposed of. To date, there is no data on the variety of medications that are disposed of. When a person takes a picture of their medication RemediChain is able to input this information into their ledger even if that medicine is not able to be donated. This information can have a lot of power. Since all medications have SNIs the manufacturer can be identified. There is a recent shift in some states to impose the incineration costs of medications onto manufacturers.\textsuperscript{138} This data could be informative to manufacturing companies as they will want to reduce their operational spend on incineration costs which could lead to wider normative conversations on switching prescription packages to blister packs to allow for more opportunities to donate, or insurance companies understanding medication use.\textsuperscript{139}

The advice that Dr. Baker shared on how to build a successful drug recycling program is to first guarantee the quality of the medicine. He believes the system’s integrity needs to be explicitly demonstrated.\textsuperscript{140} This is why RemediChain applied for a grant that will focus on quality testing.\textsuperscript{\textsuperscript{141}} The test is about $200 a drug and it will look at the active ingredients in the medications to ensure on average donated medications are within the FDA accepted bounds.\textsuperscript{142} Second, Dr. Baker recommends to consider the use of a blockchain.\textsuperscript{143} Since Italy’s healthcare is universal, the government is the predominant buyer of medications it is an ideal application for blockchain due to the more simple network chain. There is an ability for Banco Farmacéutico to scale and benefit from a blockchain based system.\textsuperscript{144}

\textsuperscript{136} Id.
\textsuperscript{137} Mulcahy, supra note 133.
\textsuperscript{138} Phone Interview with Dr. Phil Baker, Founder, Good Shepherd Pharmacy & RemediChain, (Sept. 25, 2020).
\textsuperscript{139} Phone Interview with Phil Baker, Founder, Good Shepherd Pharmacy & RemediChain, (Sept. 25, 2020).
\textsuperscript{140} Id.
\textsuperscript{141} Id.
\textsuperscript{142} Id.
\textsuperscript{143} Id.
\textsuperscript{144} Phone Interview with Phil Baker, Founder, Good Shepherd Pharmacy & RemediChain, (Sept. 25, 2020).
B. International Drug Donation Programs

Medications distributed outside the U.S. for humanitarian aid are recommended to follow the World Health Organization’s “Guideline for Drug Donations” at Department of Essential Drugs and Other Medicines, World Health Organization, 1211 Geneva 27, Switzerland. This guidance is not as stringent in comparison to U.S. drug recycling laws. It is interesting to note, the FDA in the U.S. discourages individuals or small groups from donating drugs internationally for humanitarian efforts as it may not meet the quality requirements for use in humanitarian efforts. The FDA believes that any humanitarian drug donations should be limited to large quantities as it is more cost-effective to the relief organization.

1. AID for AIDS (AFA)

AID for AIDS (AFA) operates the largest HIV Medicine Recycling Program in the world. Since its founding in 1996, AFA has sent ~$160 million worth of medication to over 20,000 people in 59 countries through its Access to Treatment Program. AFA accepts donations from anyone and allows unsealed bottles so long as they are unexpired. Over 80% of medicine donations to AFA come from individuals.

In order to donate AFA asks to follow these instructions:

1. If you live in the New York Metropolitan Area, please check the list of drop-off points available in that area to avoid incurring packaging and shipping expenses.
2. Please remove the names and addresses of all individuals from prescription bottles in order for us to comply with privacy and confidentiality laws. Always leave name of the medicine and expiration date visible.
3. Please place all pill bottles in a (sealable) plastic bag and place this bag inside a padded envelope or cardboard box. All pill bottles should be securely closed. Please: do not send any loose capsules or tablets inside a plastic bag or box!
4. Please fill out the “Donor card,” print it, and place the card inside the envelope or box. If you would like to keep your donation anonymous, please still fill out the other information requested which enables us track donations and monitor trends.

145 Guidelines for Drug Donations, WORLD HEALTH ORGANIZATION (Revised 1999), available at https://perma.cc/WK6V-7KNJ.
146 See Questions and Answers for Public Donating Drugs to International Humanitarian Relief Efforts, FDA, available at https://perma.cc/3LCN-E7HA.
147 Id.
148 Access to Treatment and Case Management, AID FOR AIDS, https://perma.cc/T8K2-7BKN.
149 Id.
150 Id.
151 Id.
152 Id.
2. Recycled Aids Medicine Program (RAMP)

RAMP is a 501(c)(3) non-profit organization fully operated by dedicated volunteers.\textsuperscript{153} The organization gathers and delivers HIV medications at no costs to partner organization overseas.\textsuperscript{154} Their current overseas recipients are in Chile (Laura Rodríguez Foundation- Santiago, Chile), Zimbabwe (Mother of Peace/Queen of Peace - Mutoko, Zimbabwe), and Beijing, China.\textsuperscript{155}

I had the privilege to talk with Howard Edelstein, the current President of RAMP, who was able to give me his insight into RAMP operations and recommendations for Banco Farmacéutico.

The first important note about RAMP is that it is not regulated by U.S. drug repository laws as its end users are not in the U.S. \textit{See World Health Organization “Guidelines for Drug Donations”} RAMP accepts HIV medications that are opened or unopened from anyone, including individuals. RAMP has multiple ways for someone to donate. First, there are donation bins at various locations around San Francisco, California. The only people allowed to retrieve the donation bins are special designated members from their team; this is to ensure no middleman tampering or interference. Second, a person can mail in their medicine to the organization. RAMP provides free mailing, however Edelstein noted that about 98\% of people donating pay for the shipping out of their own pockets.\textsuperscript{156} He believes this can be attributed to the human desire to not waste life-saving medicine and to help others.\textsuperscript{157}

Once RAMP receives the medicine it is checked to see if it is expired and if the medicine looks altercated.\textsuperscript{158} Next, the remaining medicine is packaged to ship to one of their overseas partners who will go through their own internal venting system and be distributed to a person in need.\textsuperscript{159} Edelstein stated that out of all the medicine RAMP receives about 20\% needs to be disposed of as they are expired, and about 30\% of the medicine they receive is not HIV medications.\textsuperscript{160} He recommends that any drug donation system have a well-thought out drug disposal apparatus because of the frequency of receiving expired medications.\textsuperscript{161} He made two recommendations regarding donation bins. First, that donation bins are heavy and securely fastened as historically they have had issues with stolen...

\textsuperscript{153} Phone Interview with Howard Edelstein, CEO RAMP (Sept. 12, 2020).
\textsuperscript{154} \textit{About RAMP, RAMP} (last accessed Sept. 16, 2020), https://perma.cc/XJ73-JUFE.
\textsuperscript{155} \textit{Id.}
\textsuperscript{156} Phone Interview with Howard Edelstein, CEO RAMP (Sept. 12, 2020).
\textsuperscript{157} \textit{Id.}
\textsuperscript{158} \textit{Id.}
\textsuperscript{159} \textit{Id.}
\textsuperscript{160} \textit{Id.}
\textsuperscript{161} Phone Interview with Howard Edelstein, CEO RAMP (Sept. 12, 2020).
donation bins. The second was to eliminate middlemen in the retrieving donation bin process this is to reduce opportunity for tampering.

VI. SWOT ANALYSIS

The following is a SWOT analysis based off my research and interviews. Overall, the respective strengths of the organizations revolve around their integration of technology and operational efficiencies. Identified weaknesses for the organizations include the scale of their organization and legal constraints they may face. Opportunities arises from the potential to scale their operation into other states to have more impact. Additionally, all organization can continue to capture data to be utilized for educational purposes. Given these organization’s social focus to fill a gap in the U.S. healthcare system, I do not perceive a threat of becoming obsolete given the rising need of medications due to COVID-19. A possible threat is the potential change in legal regime structures which may mandate programs to change their operations. However, due to the initial high burden and transaction costs to pass legislation this is not ranked as an immediate high-risk potential.

<table>
<thead>
<tr>
<th>SIRUM</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Strengths</strong></td>
</tr>
<tr>
<td>• Scale of network allows collection of a vast product mix</td>
</tr>
<tr>
<td>• Sophisticated algorithm platform that incorporates forecasting metrics</td>
</tr>
<tr>
<td>• Esteemed reputation and ethos as industry leaders</td>
</tr>
<tr>
<td>• Comprehensive data collection system</td>
</tr>
<tr>
<td>• Strong partnerships creates synergic value</td>
</tr>
<tr>
<td><strong>Weakness</strong></td>
</tr>
<tr>
<td>• Waitlist to expand programs in other states—potentially a resource constraint.</td>
</tr>
</tbody>
</table>

**Opportunities**

**Threats**

---


163 SIRUM was named an Audacious Project recipient from TED. This will assist the organization to grow its operations. “In the next five years, SIRUM will deploy $770 million in life-saving medicine and prevent 1,579 tons of medication waste.” See SIRUM, The Audacious Project, https://perma.cc/R97N-63P2.
- Partnerships with more states (using Georgia as a model)
- Leverage grant money and its recognition to educate more people on their program

- Possible changes in legislation may mandate a change to their model

<table>
<thead>
<tr>
<th>RemediChain</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Strengths</strong></td>
<td><strong>Weakness</strong></td>
</tr>
<tr>
<td>Incorporation of texting and easy forms increases user base of donors</td>
<td>Will reject potential donations if there is not an immediate match as there is no inventory stock</td>
</tr>
<tr>
<td>#FlipYourScrip will pay for shipping if they find a match</td>
<td></td>
</tr>
<tr>
<td>Connects individuals with the nearest disposal center to properly dispose their medicine</td>
<td></td>
</tr>
<tr>
<td>Awards donors with a $5 Amazon gift card</td>
<td></td>
</tr>
<tr>
<td>Collects data on the types of medicines which are being disposed of</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>Opportunities</strong></th>
<th><strong>Threats</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>To allow for potential donated items that are extremely popular to be stored even if an immediate match cannot be made</td>
<td>Possible changes in legislation may mandate a change to their model</td>
</tr>
<tr>
<td>Gain funding through grants to increase operation scale</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>RAMP</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Strengths</strong></td>
<td><strong>Weakness</strong></td>
</tr>
<tr>
<td>Allows donation of sealed or unsealed medication from individuals</td>
<td>Relatively small local operation</td>
</tr>
<tr>
<td>Can ship medicine across state lines (they are also willing to pay for your shipping)</td>
<td></td>
</tr>
</tbody>
</table>

| **Opportunities** | **Threats** |
| | \begin{itemize} | Changes to the World Health Organization’s Drug Donation Guidelines | \end{itemize} |
|---|---|---|
| ● Place more donation boxes in California | ● Partner with other states to provide donation boxes to increase network scope | | ● Gain funding through grants to increase operation scale |
| AIDS Survival Project | | |
| **Strengths** | **Weakness** | |
| ● Allows donation of sealed or unsealed medication from individuals | ● Wide range of offerings it is an expensive operation to provide holistic care and to scale | |
| ● Well-known organization and established partners | | |
| ● Can ship medicine across state lines (they are also willing to pay for your shipping) | | |
| **Opportunities** | **Threats** | |
| ● Place more donation boxes in New York | ● Changes to the World Health Organization’s Drug Donation Guidelines | |
| ● Partner with other states to provide donation boxes to increase network scope | | |

**VII. General Remarks**

Throughout my research process, I was surprised by the limited public information available on the topic. NSCL is the main source of aggregated state data, which as previously mentioned SIRUM assisted to update the information. Of the information that is available there is not a comprehensive report on the actual operation processes of the programs. In order to piece together the current status of a program it requires reading statutes, state websites, newspapers, press releases, and various op-eds. These data points together paint a clearer picture of a state’s program.

I found one comprehensive report done by Lacey Brinegar Paoli called *The Impact of Medication Donation Repositories: A Policy Analysis*. This report provided a current status of programs in Georgia, Iowa, Wyoming, and Kentucky. In reviewing the available information, I found it interesting that the movement of drug recycling in U.S. is driven by dedicated leaders in the space. Seemingly, it is a relatively small community of leaders. Their leadership should be recognized and
celebrated as through their quests to help, educate, and partner with others it is propelling the success, popularity, and acceptance of drug recycling programs in the U.S. With the ongoing COVID-19 pandemic the inadequacy of the U.S. healthcare system is emphasized. This dilemma provides futile grounds for expansion of drug recycling programs as a social, environmental, and economic solution.

VIII. **Recommendations for Banco Farmacéutico**

After an evaluation of the current U.S. drug recycling programs, I recommend the following four steps to Banco Farmacéutico.  

1. **Talk to current partners:** Banco Farmacéutico should consider adopting a design thinking approach to any discussion of drug recycling policy. Fully understanding the current need, concerns, and processes of their current partners is pivotal. Banco Farmacéutico in order to have a sustainable successful program must have the buy-in from its current partners. Echoing William’s sentiment, that in order to change someone’s behavior you must ensure the mission is aligned and you are not adding more work to their workflow. Initial discussions with their partners could reveal considerations or concerns that had not been identified. Establishing a strong partnership, initially, will be beneficial in the development of a comprehensive drug recycling program. Later in the process, Banco Farmacéutico should consider conducting time trials and workflow analysis at its partner’s locations, allowing the organization to see the daily operations are at their partner sites. A design thinking approach ensures the “nitty gritty” is fine tuned.

2. **Evaluate current legal system in Italy:** Knowledge on the current legal system around drug recycling is the first step. Next, would be to evaluate the current strengths and weaknesses of the policies and laws. I would pay particular attention to four legal concepts, first Good Samaritan laws. In order to properly align incentives, an ideal policy would limit liability from any person in the supply chain. Concerns for liability a large deterrent to the adoption of drug recycling programs in the U.S. If there are concerns about the safety of the medication, establishing a comprehensive medication examination could quell concerns. Additionally, Banco Farmacéutico could run thorough sampling testing of a certain percentage of the donations received—this is what RemediChain is in the process of completing. Second, jurisdiction limits, similar to U.S states, Italy is subdivided into provinces. Determining and understanding if all provinces will have the same regulatory scope is important to identify, then whether or not across provinces donated medicine could be sent or received. Banco Farmacéutico would want to advocate for a national regulatory scheme that is applied the same throughout all provinces.

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164 See also Playbook for a Community Charity Pharmacy, CHARITY PHARMACY (2018), HTTPS://PERMA.CC/DY5A-HLS2.
and allow open donations across provinces. In the U.S., this is a reality that will likely not happen due to the states power to regulate its internal system. Third, keep administrative duties on par with other medication regulation, as discussed throughout, in order to change behavior, the process should not be over burdensome. They will want to ensure that the regulation does not mandate more paperwork. Forth, sponsored funding in the U.S. not all programs are funded by the state, leading to the issue of how to fund basic operational expenses. Advocating for the law to allocate money to drug recycling programs would alleviate concerns about how provinces could start these programs.

3. Explore and understand possible technology integration: Both SIRUM and RemediChain offer potential viable options for Italy. The ideal would be to create a similar central matching platform algorithm like SIRUM’s. Italy should strive to establish an efficient system for donors and recipient facilities to be able to upload their surplus and need to be matched. Leveraging technology, will reduce the administrative duties placed on partners. Initially, I would recommend Banco Farmacéutico to adopt a pull method as it is more likely to be successful because this prevents issues of donated medicines sitting idle. A pull method also streamlines logistics to prevent unnecessary shipping as the medicine shipped has a predetermined demand. Note, unfortunately, this does put the burden to sort the medications on the donors. Additionally, Banco Farmacéutico should consider a blockchain integration into their platform. Blockchains provides an innovative way to ensure tracking and tracing of all medications. A centralized ledger can give insights into the overall demand of medications and areas where waste is created. A blockchain would be ideal to implement in Italy given the government provides and pays for the healthcare. With one centralized buying power it would make it easier to keep track of the ecosystem. The ability to trace the medicine at every stage of its lifecycle could subside quality concerns as well.

4. Incremental implementation and retrospectives: Banco Farmacéutico would want to consider where it would like to start and test a pilot program. The U.S. benefits from state specific policy in the sense that every state has the opportunity to cater its drug recycling program as it sees best. This comes with the benefit of testing what program may work best to launch at a national scale, but on downside it prevents for comprehensive solutions. Banco Farmacéutico should choose a pilot region and learn what works best before scaling it at large. Alternatively, if Banco Farmacéutico wanted to start their donation program to donate medications for humanitarian relief it could implement this program and eventually scale into domestic operations.

   Foundational to any program for Banco Farmacéutico is two things: 1) education 2) data. I think for a program to be successful the general public needs to know about it and its societal benefits. Second, a program needs to be able to justify itself. The collection of data helps creates this narrative. Data collection can also assist Banco Farmacéutico to evaluate nationwide trends and propose
recommendations. Data will allow Banco Farmacéutico to make informed decisions and to utilize this information to optimize its operations and effectively allocate resources.

IX. CONCLUSION

Drug recycling programs in the U.S. are regulated and empowered by each individual state. States likely to succeed in their programs are those who provide state funding, strong Good Samaritan laws, and reasonable record keeping requirements. State and organization partnerships are key to the success of some programs due to the ability to streamline technology and benefit from aggregated network distribution.

In the U.S., the non-profit SIRUM can be credited for establishing and supporting the success of many state programs. SIRUM is uniquely positioned as it effectively integrates technology to bridge gaps in resources, an attribute fundamental to the overall success of drug recycling programs. There is an immense opportunity for drug programs in the U.S. to expand in their operations. The impact of COVID-19 has increased the demand of medications as individual economic position has been negatively impacted. This is only expounded by the rising cost of medications. One of the keys to a successful program is to bolster its adoption by demonstrating their impact with data. Any organization or state should track and record the social impact of their programs as it facilitates future discussions with policymakers.

The U.S. provides unique experiences and lessons that Banco Farmacéutico can learn from as they begin to navigate how to incorporate a prescription drug donation program in Italy. My advice to Banco Farmacéutico can be segmented into four steps. First, they should talk to their current partner organizations to fully understand their ideas, concerns, and processes. Second, they need to evaluate their current legal system to identify areas where they could propose normatively positive policy. Third, they must understand the available technology and its potential integration into their drug recycling program. Ideally, Banco Farmacéutico will invest initial capital into the most efficient technology available to establish their program: I advise they look into the possibility of blockchain integration. Lastly, they should select an area to use as a pilot and ensure throughout their scaling process it is not only incremental, but retrospectives and adjustments are made to their strategy as needed. There are immense benefits to drug recycling programs. Drug recycling programs assist those in need increase their quality of life, decrease environmental waste, and are cost effective. The investment and adoption of a comprehensive drug recycling program in Italy would be immensely beneficial for its citizens.
Comparative Chart of U.S. Drug Spending in Relation to Other Countries (demonstrating that American pharmaceutical spending started taking off in the late 1990s compared with other advanced nations)


**International Comparison of Drug Spending**

American pharmaceutical spending started taking off in the late 1990s compared with other advanced nations.

**Annual retail prescription drug spending per person**
FIGURE 2

OECD Chart: Pharmaceutical spending, Total, US dollars/capita, Annual, 2015 – 2019 (showing US as the highest at $1,229/capita; Italy with $655/capita; Spain with $525/capita; Portugal with $455/capita; and Mexico as the least at $254/capita)

FIGURE 3

OECD Chart: Pharmaceutical spending as total % of GDP, Annual, 2015 – 2019 (showing Bulgaria as the highest with 2.60%; US with 1.95%; Italy with 1.55%; Portugal with 1.39%; Spain with 1.38%; and Luxemburg as the least at 0.60%)

FIGURE 4

OECD Chart: Pharmaceutical spending as total % of total health spending, Annual, 2015 – 2019 (showing Bulgaria as the highest with 35.4%; Italy with 18%; Spain with 15.3%; Portugal with 14.7%; US with 11.6%; and Denmark as the least with 6.4%).

Organization for Economic Co-operation and Development (OECD), Pharmaceutical spending as total % of health spending, OECD Data, https://perma.cc/4LKC-BN7E.
OECD Chart: Health spending total/government compulsory/voluntary US dollars/capita Annual, 2015 – 2019 (showing US as the highest with total $11,072/capita, government compulsory $9,386/capita, voluntary $1,685; Italy total $3,649/capita, government compulsory $2,706/capita, voluntary $943/capita; Spain total $3,616/capita, government compulsory $2,560/capita, voluntary 1,059/capita; Portugal total $3,379, government compulsory $2,069, voluntary $1,310/capita; and North Macedonia as the least with total $934/capita, government compulsory $640/capita, voluntary $303/capita)

FIGURE 6

OECD Chart: Health spending total/government compulsory/voluntary % of GDP (showing US with the highest total at 17%; Portugal at 9.6%; Spain at 9%; Italy at 8.7%; and Indonesia with the lowest at 3%)

FIGURE 7

Adults Who Cited Cost as a Reason for Skipping Prescription or Doses, by Health Status, 2016

FIGURE 8

Adults Who Cited Cost as a Reason for Skipping Prescription or Doses, by Health Status, 2016 (showing 33% of US citizens who were uninsured reported cost as a reason compared to 14% of US citizens with insurances).


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Exhibit 6

**Adults Who Cited Cost as a Reason for Skipping Prescriptions or Doses, 2016**

Data: 2016 Commonwealth Fund International Health Policy Survey of Adults in 11 Countries.

Low-Income U.S. Adults from 19 to 64 with Household Poverty Status at 200% of Federal Poverty Level or Lower Who Cited Cost as a Reason for Skipping Medicine (illustrating yearly trends of skipping medicine because of cost)


2017 US Data of Cost Savings from Buying the Same Medication In Foreign States (showing that because prescription drugs cost more in the U.S. than in most anywhere else in the world why Americans are illegally importing drugs from other countries).

FIGURE 11

Prescription Drug Donation and Reuse State Programs in the U.S. (showing which states have current enacted operational programs or not)

<table>
<thead>
<tr>
<th>State</th>
<th>Enacted Law? (Y/N)</th>
<th>Does State Board of Pharmacy Allow a Drug Repository Program?</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Alabama</td>
<td>Y</td>
<td>N</td>
<td>Signed into law in 2002.</td>
</tr>
<tr>
<td>Alaska</td>
<td>N</td>
<td>Y</td>
<td>Bills have been introduced regarding drug repository programs, but not enacted.</td>
</tr>
<tr>
<td>Arkansas</td>
<td>Y</td>
<td>Y</td>
<td>Signed into law in 2005.</td>
</tr>
<tr>
<td>Colorado</td>
<td>N</td>
<td>N</td>
<td>Repealed in 2018.</td>
</tr>
<tr>
<td>Delaware</td>
<td>N</td>
<td>Y</td>
<td>Bills have been introduced regarding drug repository programs, but not enacted.</td>
</tr>
<tr>
<td>Guam</td>
<td>Y</td>
<td>Y</td>
<td>Signed into law in 2004.</td>
</tr>
<tr>
<td>Hawaii</td>
<td>N</td>
<td>N</td>
<td>Repealed in 2010.</td>
</tr>
<tr>
<td>Idaho</td>
<td>Y</td>
<td>Y</td>
<td>Signed into law in 2009.</td>
</tr>
<tr>
<td>Indiana</td>
<td>Y</td>
<td>Y</td>
<td>Signed into law in 2004.</td>
</tr>
<tr>
<td>Kentucky</td>
<td>Y</td>
<td>Y</td>
<td>Signed into law in 2005.</td>
</tr>
<tr>
<td>Maine</td>
<td>N</td>
<td>N</td>
<td>In 2017, Legislature proposed bill to require the Board of Pharmacy to create rules establishing a dispensing process; however, it failed.</td>
</tr>
<tr>
<td>Massachusetts</td>
<td>N</td>
<td>N</td>
<td>Law repealed in 2012.</td>
</tr>
<tr>
<td>Minnesota</td>
<td>Y</td>
<td>Y</td>
<td>Signed into law in 2007.</td>
</tr>
<tr>
<td>Mississippi</td>
<td>Y</td>
<td>Y</td>
<td>Signed into law in 2017.</td>
</tr>
<tr>
<td>Missouri</td>
<td>Y</td>
<td>Y</td>
<td>Signed into law in 2004.</td>
</tr>
<tr>
<td>Nevada</td>
<td>Y</td>
<td>Y</td>
<td>Signed into law in 2003.</td>
</tr>
<tr>
<td>New Jersey</td>
<td>N</td>
<td>Y</td>
<td>No laws enacted.</td>
</tr>
<tr>
<td>New Mexico</td>
<td>Y</td>
<td>Y</td>
<td>Signed into law in 2011.</td>
</tr>
<tr>
<td>New York</td>
<td>N</td>
<td>Y</td>
<td>2016-2016 legislative session passed law directing the commissioner to create regulations for the reuse and redistribution of prescriptions.</td>
</tr>
<tr>
<td>North Carolina</td>
<td>Y</td>
<td>Y</td>
<td>Signed into law in 2009.</td>
</tr>
<tr>
<td>Oregon</td>
<td>Y</td>
<td>Y</td>
<td>Signed into law in 2009.</td>
</tr>
<tr>
<td>Rhode Island</td>
<td>N</td>
<td>N</td>
<td>Repealed in 2013.</td>
</tr>
<tr>
<td>South Carolina</td>
<td>N</td>
<td>N</td>
<td>Bills have been introduced regarding drug repository programs, but not enacted.</td>
</tr>
<tr>
<td>South Dakota</td>
<td>N</td>
<td>N</td>
<td>Signed into law in 2014.</td>
</tr>
<tr>
<td>Utah</td>
<td>Y</td>
<td>Y</td>
<td>Signed into law in 2005.</td>
</tr>
<tr>
<td>Vermont</td>
<td>N</td>
<td>N</td>
<td>Repealed in 2018.</td>
</tr>
<tr>
<td>Washington</td>
<td>Y</td>
<td>Y</td>
<td>Signed into law in 2013.</td>
</tr>
<tr>
<td>Washington, D.C.</td>
<td>N</td>
<td>N</td>
<td>Bills have been introduced regarding drug repository programs, but not enacted.</td>
</tr>
<tr>
<td>West Virginia</td>
<td>N</td>
<td>Y</td>
<td>Bills have been introduced regarding drug repository programs, but not enacted.</td>
</tr>
</tbody>
</table>
FIGURE 13

Get Started with Good Pill in 3 Easy Steps

Good Pill, https://perma.cc/ND78-YFSE.

1. Your patient registers with Good Pill

Patients can see if our stock of over 450 medications includes what they need. After registering online, they can let us know whether to transfer existing prescriptions or have their provider call in new ones to Good Pill.

2. Providers call in prescriptions

We accept prescriptions by e-script, mail, fax, or phone. If the prescriptions were already sent to another pharmacy, we’ll be happy to request a transfer from that pharmacy instead (remember to change the preferred pharmacy for next time). If we don’t have the medication in stock, we’ll automatically transfer the prescription to the patient’s back up pharmacy. Learn more here.

3. Your patient gets their medication

We dispense medication in 90 day supplies, as appropriate, and deliver to patients’ homes in 5-7 days. We automatically send tracking info, reminders, and refills to help patients stay on track.

FIGURE 14

Table Showing Whether Good Pill is Right for Someone


Is Good Pill right for your patients?

✔ They have a Georgia mailing address or PO box

✔ Their medication is in our current stock list

✔ They are uninsured or insured with a high copay or deductible

✔ They have trouble getting to the pharmacy

✗ They are located outside of Georgia

✗ They need insulin or opioids

✗ Medication is needed same day

✗ Patient prefers in-person pickup
FIGURE 15

Iowa SafeNetRx Program Statistics (showing the success of the program to serve in need patients)


FIGURE 16

How to donate to SIRUM in 5 Steps

FIGURE 17

How to Sign-Up as a Partner Site


Register
Answer a few simple questions and sign our agreement to donate or receive medicine.

Box it up
We’ll send everything you need to ship. Place medicines in the provided box, and we’ll schedule a pickup through FedEx.

Stay confidently compliant
We provide a full record of the donation, along with the impact it had on the community.
FIGURE 18

Option Plans for Partner Organization


FIGURE 19

How the Good Shepard Pharmacy’s Program Works

GOODSHEPRx, https://perma.cc/T2Z6-CJ9R.
FIGURE 20

Good Shepard Pharmacy’s Pricing Options

GOODSHEP RX, https://perma.cc/T2Z6-CJ9R.