



# Penis Enlargement, Cheap Viagra, and Noni Juice: Evaluating and Winning the War Against Health Product Spam

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**Penis Enlargement, Cheap Viagra, and Noni Juice:  
Evaluating and Winning the War Against Health Product Spam**

Andrew Sing Huo Ting

Harvard Law School Class of 2004

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**Abstract.** Unsolicited commercial e-mail, or “spam”, is an exponentially increasing annoyance for millions of Americans every day. Health product spam – spam which promotes drugs, dietary supplements, and medical devices – is both annoying and dangerous, because fraudulent health products are at best a waste of money and at worst hazardous to health. This paper discusses four spam case studies – 21 CENTURY MIRACLE PRESCRIPTIONS, Noni Juice, Pinnacle Penis Enlargement Pills, and Sleep Angel – to evaluate

the effectiveness of the FDA, the FTC, and state consumer protection laws in stopping fraudulent health product spam. This paper also analyzes the impact of the federal CAN-SPAM Act, federal and state computer crime laws, and technological remedies in actual reduction of spam. Combining the best lessons from health and anti-spam regulatory law, this paper concludes with an array of proposals that would better regulate e-mail advertising of health products.

## I. Introduction

“HERBAL ENERGIZER... SUPER FAT BURNER!”<sup>1</sup> “Pheromones 4 u”<sup>2</sup> “Pill to Increase Your Ejaculation by 581%”<sup>3</sup> “Prescriptions Without Doctors [sic] Appointment!”<sup>4</sup> “You Decide: Is Age-Reversal Possible?”<sup>5</sup> These are actual subject lines from unsolicited commercial e-mails received by millions of Americans every day. Unsolicited commercial e-mail, colloquially called “spam”,<sup>6</sup> is more than a daily annoyance to be deleted in your inbox. Spam costs time and money for businesses which try to block incoming spam, for employees in lost productivity, and for individuals who are duped into purchasing fraudulent products. Fraudulent health product spam is especially threatening because buying fraudulent health care products is at best a waste of money and at worst hazardous to health.

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<sup>1</sup>All e-mail references in this paper are to actual unsolicited e-mail archived at websites dedicated to fighting spam. E-mail from The Great Spam Archive, at <http://www.annexia.org/spam/messages/Junk26/014.html> (sent by “moneyman@aol.com”, Jan. 24, 1998).

<sup>2</sup>E-mail from The Great Spam Archive, at <http://www.annexia.org/spam/messages/spam.054/106.html> (sent by “beat-her4290@yahoo.com”, Sep. 22, 2001).

<sup>3</sup>E-mail from The Great Spam Archive, at <http://www.annexia.org/spam/messages/spam.055/534.html> (sent by “hva2sjvuwng@hotmail.com”, Nov. 29, 2001).

<sup>4</sup>E-mail from The Great Spam Archive, at <http://www.annexia.org/spam/messages/spam.052/089.html> (sent by “koke@yachtemail.com”, Aug. 10, 2001).

<sup>5</sup>E-mail from The Great Spam Archive, at <http://www.annexia.org/spam/messages/spam.039/009.html> (sent by “marketing27@uole.com”, Oct. 29, 2000).

<sup>6</sup>Hormel Foods Corporation notes that “the term ‘spam’ was adopted as a result of the Monty Python [movie] skit in which our SPAM meat product was featured. In this skit, a group of Vikings sang a chorus of ‘spam, spam, spam . . .’ in an increasing crescendo, drowning out other conversation. Hence, the analogy applied because UCE [unsolicited commercial e-mail] was drowning out normal discourse on the Internet.” At <http://www.spam.com/ci/ci.in.htm> (last visited Apr. 7, 2004).

This paper critically evaluates the successes and failures of the federal and state regulatory agencies who are leading the fight against fraudulent health product spam. Section II frames the mounting problem of spam and the subset of fraudulent health product spam. Section III introduces four health product spam case studies – 21 CENTURY MIRACLE PRESCRIPTIONS, Noni Juice, Pinnacle Penis Enlargement Pills, and Sleep Angel – and analyzes how each spam is representative of Internet health product fraud for drugs, dietary supplements, and medical devices. Section IV analyzes the Food and Drug Administration’s (“FDA”) response in these four case studies to illustrate the FDA’s successes and failures in regulating fraudulent health product spam. Section V evaluates the Federal Trade Commission’s (“FTC”) track record in stopping fraudulent health product spam. Section VI addresses the impact of the federal CAN-SPAM Act of 2003 and anti-spam technology on reducing health product spam. Section VII highlights California’s unfair competition and computer crime laws as a model of how state laws can also regulate health product spam. Section VIII evaluates the efficacy of private legal and technological remedies in stopping health product spam.

Combining the best lessons learned from these health and anti-spam regulatory experiences, Section IX proffers a battery of legislative proposals and enforcement reforms that will help win the fight against fraudulent health product spam. Finally, Section X concludes by generally framing the laws, regulatory actions, and technologies that will all be necessary to reduce fraudulent health product spam.

## **II. The Alarming Rise of Spam**

This section discusses the alarming rise of spam, the economics that make spam profitable, and then analyzes the growing problem of fraudulent health product spam.

#### A. The Volume and Economics of Spam

Spam is clearly a growing crisis. Timothy Muris, the Chairman of the Federal Trade Commission, ominously asserts that “[T]he volume of unsolicited email is increasing exponentially and . . . we are at a ‘tipping point,’ requiring some action to avert deep erosion of public confidence that could hinder, or even, for many, destroy, e-mail as a tool for communication and online commerce.”<sup>7</sup>

The Rapid Increase of E-Mail and Mobile Phone Spam. True to Muris’s words, spam has already reached the tipping point of overwhelming legitimate e-mail. In January 2004, 60% of all Internet e-mail was spam, up from 40% of all e-mail in January 2003.<sup>8</sup> Analysts for Brightmail, the anti-spam market leader which filtered 800 billion e-mail messages (15% of the world’s total e-mail traffic) in 2003, estimate that spam will eventually peak at 80% of all e-mail traffic.<sup>9</sup>

Spam, however, is not simply an American or an e-mail problem. The 38 million customers of DoCoMo, Japan’s largest wireless company, receive 30 million pieces of spam a day on their cell phones.<sup>10</sup> Before Japan passed anti-spam legislation, these 38 million customers received 150 million pieces of spam a day. In

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<sup>7</sup>FTC Chairman Timothy Muris, The FTC and the Future Development of U.S. Consumer Protection Policy, Remarks at the Aspen Summit (Aug. 19, 2003), available at <http://www.ftc.gov/speeches/muris/030819aspen.htm>.

<sup>8</sup>Press Release, Brightmail, Spam Levels Will Peak at 80% of All Internet E-Mail, at [http://www.brightmail.com/pressreleases/021004\\_apac-80-percent-spam.html](http://www.brightmail.com/pressreleases/021004_apac-80-percent-spam.html) (Feb. 10, 2004).

<sup>9</sup>Id.

<sup>10</sup>Legislative Efforts to Combat Spam: Joint Hearing before the Subcomm. on Commerce, Trade, and Consumer Prot. and the Subcomm. on T 108th Cong. (2003) (statement of Rep. Rush Holt).

Europe, 65% of mobile phone users report receiving up to five unsolicited text messages on their Internet-enabled phones each week.<sup>11</sup> CEOs of mobile phone companies admit that mobile phone spam is increasing rapidly, and may eventually assume the epidemic proportions of Internet e-mail spam.<sup>12</sup> While Congress has proposed legislation against wireless spam,<sup>13</sup> the volume of e-mail spam currently dwarfs the volume of mobile phone spam in the U.S.. Therefore, e-mail spam remains the focus of this paper.

Spam Propagates Through Dangerous Viruses. Spam is increasingly packaged with “Trojan horse” viruses that surreptitiously infect the recipient’s computer, turning the computer into a “zombie” which can be controlled without the owner’s knowledge to send out – surprise! – even more spam. Experts believe that *two thirds* of all spam is sent by zombies infected by Trojan horses like the 2003 SoBig.F spam virus.<sup>14</sup> The damage from spam viruses, however, is not limited to sending out more spam. Once infected, any files on the recipient’s computer can be accessed by the virus writer, compromising any sensitive data stored on the machine.<sup>15</sup>

Economics of Spam: Why Spam is Profitable for Spammers. Spammers can send out billions of spam messages because spam is incredibly cheap. While direct mail costs \$1.21 per recipient, spam costs only \$0.0005 per recipient.<sup>16</sup> This difference translates into profitability with lower response rates: while direct mailers

<sup>11</sup>Mobile Phones Face “Spam Epidemic”, CNN, at <http://www.cnn.com/2004/WORLD/europe/02/19/globaloffice.phonespam/index.html> (Feb. 18, 2004).

<sup>12</sup>Id.

<sup>13</sup>See Legislative Efforts to Combat Spam, *supra* note 10.

<sup>14</sup>Massive Rise in Spam Down To SoBig Virus, at <http://www.silicon.com/research/specialreports/thespamreport/0,39025001,39117272,00.htm> (Dec. 9, 2003).

<sup>15</sup>Id.

<sup>16</sup>Paul Judge, The State of the Spam Problem, *Educause Review*, Sept./Oct. 2003, at 60, available at <http://www.educause.edu/ir/library/pdf/erm0357.pdf>.

require a response rate of 2%, spammers only need a response rate of 0.001% to be profitable – in other words, spammers only need five responses for 500,000 e-mails sent!<sup>17</sup> Because spammers can send out more than 1,000,000 e-mail messages in 1 hour, this business model works.<sup>18</sup>

Why is spam so cheap? Most of the costs of spam are borne not by spammers but by Internet service providers who maintain the Internet infrastructure that transmits and stores e-mail messages. These spam-related costs amount to more than \$500 million annually.<sup>19</sup> America Online alone has blocked more than a billion spam messages in a single 24-hour period.<sup>20</sup> Spammers clearly benefit by shifting the costs of spam to others.

Economics of Spam: Spam Sells Products. In August 2003, the Direct Marketing Association cited a study finding that in the preceding 12 months, 45.8 million Americans purchased products and services in response to a legitimate e-mail advertisement, accounting for at least \$7.1 billion in sales.<sup>21</sup> 11 million Americans, representing 9 percent of e-mail users, made at least one purchase of products and services in response to *unsolicited* e-mail advertisements.<sup>22</sup> In other words, spam works. While more than 90% of Americans throw spam away, spam still results in the purchase of hundreds of millions of dollars in products – enough to keep the spammers in business.

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<sup>17</sup>Id.

<sup>18</sup>Jefferson Lankford, Spam: The End of E-mail?, Arizona Attorney, July/Aug. 2003, at 14.

<sup>19</sup>Id.

<sup>20</sup>Id.

<sup>21</sup>Press Release, Direct Marketing Association, DMA Statement re: Operation Slam Spam, at <http://www.the-dma.org/cgi/disppressrelease?article=484> (Aug. 22, 2003).

<sup>22</sup>Id.

Economics of Spam: The \$20 Billion Cost of Spam. In 2004, spam is projected to cost businesses more than \$20 billion worldwide.<sup>23</sup> This is a sharp increase from the \$13 billion cost of spam in 2003.<sup>24</sup> Costs result from workers' lost productivity, because the average worker spends 15 minutes a day reviewing and deleting unwanted messages, or searching for messages that were inadvertently deleted or blocked by spam filtering software.<sup>25</sup> Costs also result from businesses buying more computer hardware to handle the increase in e-mail traffic and expanding help desk support for annoyed users.

#### B. Hundreds of Billions of Fraudulent Health Product Spam Messages

7-10% of Spam is Health Product Spam. In its 2003 False Claims in Spam report, the FTC's Division of Marketing Practices reviewed a random sample of 1,000 spam and found that 10% was health product spam promoting dietary supplements, disease prevention, and organ enlargement.<sup>26</sup> A January 2004 Brightmail study found that 7% of spam contained health-related product and service marketing messages.<sup>27</sup> Despite this relatively low percentage, Brightmail found that the two most common types of spam messages in 2003 were for body part enlargement ("Get Bigger, 100% Proven Results") and online pharmacies ("You can order PAIN MEDS, Anti-Depressants, Weight Loss Meds Online").<sup>28</sup>

Although only 7-10% of spam is health care related, this still results in about 250 billion health product spam messages sent to consumers.<sup>29</sup> Even worse, most of those 250 billion health product spam messages

<sup>23</sup>Spam Costs \$20 Billion Each Year in Lost Productivity, TechNewsWorld, at <http://www.technewsworld.com/perl/story/32478.html> (Dec. 29, 2003).

<sup>24</sup>Study: Spam costs businesses \$13 billion, CNN, at <http://www.cnn.com/2003/TECH/biztech/01/03/spam.costs.ap/> (Jan. 5, 2003).

<sup>25</sup>Spam Costs \$20 Billion Each Year in Lost Productivity, *supra* note 23.

<sup>26</sup>Div. of Mktg. Practices, FTC, False Claims in Spam, at 2 (2003), available at <http://www.ftc.gov/reports/spam/030429spamreport.pdf>.

<sup>27</sup>Brightmail, Brightmail Spam Statistics, at <http://www.brightmail.com/spamstats.html> (last visited Apr. 7, 2004).

<sup>28</sup>Press Release, Brightmail, Brightmail Reports on Spam Trends of 2003, at [http://www.brightmail.com/pressreleases/121803\\_spam\\_2003.html](http://www.brightmail.com/pressreleases/121803_spam_2003.html) (Dec. 18, 2003).

<sup>29</sup>In 2003, more than 5 trillion e-mails were sent, and about 50% – 2.5 trillion messages – were spam. Therefore, about 250



were false.

Most Spam, Including Health Product Spam, is False. The FTC's 2003 False Claims in Spam report found that 66% of all spam was false, either in the text of the message, the sender's name, or the recipient's name.<sup>30</sup> Falsity rose to 69% for health product spam.<sup>31</sup> In 2003, then, about *175 billion* false health care e-mail messages were sent to unsuspecting consumers.<sup>32</sup>

In short, the health product spam industry, with its lack of accountability, has created a "Wild West" culture for health care product e-mail marketing. The FDA and the FTC have clearly failed to combat this rising tidal wave of deception. Before analyzing why the FDA and FTC's actions have been inadequate, however, let us take a closer look at the horns of the beast.

### **III. Analysis of Four Case Studies of Representative Health Product Spam**

This section analyzes four case studies from each of the four general categories of health product spam: prescription drugs, fraudulent drugs, dietary supplements, and medical devices. General observations about the characteristics of each health product spam category are followed by more concrete observations from the text of a representative spam message. All typos and grammatical mistakes from the original spam messages have been preserved, although some redundant text has been removed for brevity. Section IV addresses the specific regulatory actions taken in response to these case studies and the general regulatory actions

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billion – or 10% – was health product spam.

<sup>30</sup>Div. of Mktg. Practices, FTC, supra note 26, at 10.

<sup>31</sup>Id.

<sup>32</sup>See supra note 29. 69% of 250 billion total health product spam messages is about 175 billion false health product spam messages.

appropriate to each category of health product spam.

A. Spam Promoting Prescription Drugs – “21 CENTURY MIRACLE PRESCRIPTIONS”

Spam promoting prescription drugs usually takes the form of messages linking to online pharmacies where the recipient can obtain prescription drugs with very minimal (or nonexistent) online approval. These “rogue” pharmacies do not satisfy the legal standard for dispensing prescriptions and the drugs they sell are often adulterated and hazardous to health. The following is a representative example.

\* \* \* \* \*

**Pharmaceutical Wonder Drugs !! Online Ordering !!...**<sup>33</sup>

21 CENTURY MIRACLE PRESCRIPTIONS

NOW AVAILABLE ONLINE....

ORDER DIRECTLY FROM YOUR COMPUTER...

NO INCONVENIENCE OR EMBARRASSMENT TO YOU.

No hassles, no waiting rooms – everything completed online.

ONLINE ASSESSMENT BY U.S. PHYSICIANS  
IMMEDIATE PRESCRIPTION DISPENSING

<sup>33</sup>E-mail from The Great Spam Archive, at <http://www.annexia.org/spam/messages/spam.055/148.html> (sent by “bekir2009632@msn.com”, Nov. 11, 2001).

IF THE PHYSICIAN does not approve you. NO CHARGE.

Complete information is available at our Web Site,

where orders may be placed directly. Credit cards accepted.

ORDERS ARE SHIPPED WORLDWIDE . . .

Prescriptions delivered discreetly to your door.

*[Omitted: Advertisements to induce the recipient to buy Celebrex, Viagra, Propecia, Xenical, Claritin, Zyban, and Renova. These advertisements were not fairly balanced because they stressed only the benefits and omitted the risks of these drugs]*

Patients are assessed online for their suitability to take ANY of these breakthrough pharmaceutical drugs and if approved their prescription is dispensed immediately with further ADDITIONAL refills...

Go to: <http://megavisit.com/meds/?aid=214346> <sup>34</sup>

\* \* \* \* \*

Spam like “21 CENTURY MIRACLE PRESCRIPTIONS” promoting dubious online pharmacies is very common. To avoid being identified by enforcement authorities, these online pharmacies constantly move from website to website. Thus, spam with links to rogue pharmacies expires quickly, only to be replaced by spam with links to new rogue pharmacies.

B. Spam Promoting Fraudulent Drugs – “NONI JUICE CURE?”

Miracle all-in-one cures for disease, touted since time immemorial, have moved online. Who knew that

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<sup>34</sup>As of Apr. 7, 2004, this website was no longer operational.

“Noni Juice” could cure asthma, arthritis, sexual dysfunction, cancer, and a host of other ailments? This audacious promotion reflects the breadth and depth of fraudulent drug spam claims to cure a bewildering array of diseases, backed up by equally fraudulent medical research and exaggerated testimonial claims.

This case study is especially amusing because “Christian Brothers Health Corp” is apparently very concerned that the recipient might buy noni juice from its other fraudulent spamming competitors. Also note Christian Brothers Health Corp’s attempt to persuade the recipient to “stack” its other holistic therapies – also conveniently available, of course, from its website.

\* \* \* \* \*

### **NONI JUICE CURE?<sup>35</sup>**

Suffering from asthma, arthritis, sleeping problems, cancer, skin problems, digestion problems, sexual disfunction or other ailments?

#### **Noni juice considered the greatest health discovery since DNA**

This info is from the Daily News, July 6th 2001. John Hopkins Medical School, U.S. Govt. Natl. Institute of Health, U. of Calif. Medical School, Boston U Medical School and 4 Nobel Prize-Winning Doctors!

The group monitored that intake Noni Juice daily have been found to have the following characteristics:

- These people do not reach middle age until their late 80’s and old age well past 110
  
- Their hair never turns gray - they never go bald - they keep a full set of teeth...even into their 100’s and never need hearing aids or glasses in their entire lives.

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<sup>35</sup>E-mail from The Great Spam Archive, [at](http://www.annexia.org/spam/messages/spam.051/301.html) <http://www.annexia.org/spam/messages/spam.051/301.html> (sent by “bhalpher@tfz.net”, Jul. 27, 2001).

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The women do not reach menopause until their early 70's...while the men retain full virility and the same sexual capability at age 85 or even 95 as they enjoyed in their 20's and 30's

- None of these people - not at any age - ever suffer from arthritis, bursitis or rheumatism.

- 

Serious and often fatal diseases such as diabetes, cancer, heart attacks, strokes and Parkinson's are virtually unknown...and for this select group of people, lesser afflictions such as colds, viruses, headaches, backaches, heartburn and insomnia, simply do not exist.

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Perhaps most amazing of all - they never take vitamin pills, minerals or any supplements whatsoever.

They are a select group of French men and women, who have been carefully monitored by medical science for the past number of years. They come from all walks of life...reside in central Polynesia...perform the same daily activities as the average American family - and are no different than you and I...except for one very significant, major difference.

They have all been directed to eat a very special kind of food at least once a day...a food virtually unknown in any other part of the world...a food that medical doctors in this country firmly believe is:

**The world's richest source of cellular rejuvenating enzymes- that fortify the immune system, regenerate your body's cells and actually reverse the aging process!**

The name of this anti-aging, life-extending food is NONI, (from the French phrase, non-annee - never age) . . . . The best source is when the noni has the seed extract inside. Only Christian Brothers Health Corp has the noni seed extract included. Please call 800-395-7379 to order noni juice today. Noni is normally \$42 per bottle, however Christian Brothers Health Corp price is \$34 for one bottle or \$122 for four bottles. Wholesale customers must call for wholesale prices.

You will find that our price is the most affordable and that our noni is the thickest (not watered down as others are) Our Noni comes from Dominica. Dominica soil is richest in soil minerals among the other Caribbean islands due to the volcanic virgin soil the Noni fruit comes from. We challenge you to find another place that has anywhere near as strong and potent a juice as ours or as inexpensive. Noni Juice is normally between \$40 and \$60 per bottle, has less then 90% Noni inside and does not include the special extract from the seed as does ours. Our Noni juice is over 95% Noni, includes the extract from the seed and is less expensive then any other Noni on the web because network marketing is not involved.

Don't lose this e-mail! Pass it onto a friend who may need some health hints.

Stacking is the best way to recover from disease. Stacking involves putting a few different holistic therapies together to beat a specific ailment. Please visit our websites for more info.

Directions and Ordering info

- Noni should be taken twice per day between 2-4 ounces 1/2 hour before meals.
- To order call 800-395-7379.
- Ask for info on our other products such as Coral calcium, Enzymes, Herbs for the Kidneys, Heart, Blood pressure, Prostate, Liver, Pancreas, Dms0, etc. Reply to this e-mail with the word health in the subject line to receive this info or call.

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These astonishing claims made about noni juice are ridiculous. Yet three years after this e-mail was sent, a Google search for "Noni Juice" yielded 122,000 hits and dozens of commercial websites dedicated to selling noni.<sup>36</sup> Noni juice is still a profitable venture – even after FDA regulatory actions to curb noni juice claims, which is discussed in Section IV.

Noni juice is only one of many fraudulent drugs promoted by spam. Spam promoting fraudulent drugs, however, is dwarfed compared to spam promoting dietary supplements.

C. Spam Promoting Dietary Supplements – "PINACLE PILLS"

<sup>36</sup>The Google search was performed on Apr. 7, 2004. The top commercial website results included: <http://www.noni-juice-plus.com/>, <http://www.nonidirect.com/>, <http://www.noni juice.us/>, <http://www.nonistation.com/>, <http://www.nonilink.com/>, and <http://www.tahitiannoni.com/>.

Most health product spam is not aggressive enough to make the “cure and treatment of disease” claims which are most likely to incite FDA action. Taking advantage of the lax legal latitude of dietary supplement regulation, most products confine themselves to “affect the structure and function of the body” claims. Such claims still provide adequate (and ample) room for exaggeration. As a result, dietary supplement spam is the most frequent type of health product spam:

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**Breast Enhancement Cream** (“Women increased their bust size by over 2 inches”)<sup>37</sup>

- **Celtic Sea Algae** (“In Okinawa, Japan, you will find very little disease or doctors”)<sup>38</sup>
- **Exotic Herbs** (introducing “Offering[s] for your ‘Sensitive’ Delight” such as “‘Seventh Heaven’ Kathmandu Temple Kiff (tm); a viripotent cannabis alternative for blissful regressions of vexatious depressions” and “Sweet Vjestika Aphrodisia Drops (tm); An erotic aphrodisia; sexual intensifier / enhancer liquid amalgamated extract for MEN and WOMEN.”)<sup>39</sup>
- **Pill to Increase Your Ejaculation by 581%** (“Experience both a huge increase in the amount of semen you ejaculate and longer lasting more intense orgasms”)<sup>40</sup>
- **Secerts [sic] of Staying Young** (“As seen on NBC, CBS, CNN, and even Oprah! The health discovery that actually reverses aging while burning fat, without dieting or exercise!”)<sup>41</sup>
- **Shocking FDA Report May Save Your Life!** (hawking, oddly enough, a product called “Sir Jason Winter Intestinal Cleanser”)<sup>42</sup>

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<sup>38</sup>E-mail from The Spamarchive, at <http://mellin.org/spamarchive/view.jsp?id=12006> (added Apr. 10, 2003).

<sup>39</sup>E-mail from The Great Spam Archive, at <http://www.annexia.org/spam/messages/spam.049/214.html> (sent by “uksyz@bluemail.dk”, May 19, 2001).

<sup>40</sup>E-mail from The Great Spam Archive, at <http://www.annexia.org/spam/messages/spam.055/534.html> (sent by “hva2sjvuwnq@hotmail.com”, Nov. 29, 2001).

<sup>41</sup>E-mail from The Great Spam Archive, at <http://www.annexia.org/spam/messages/spam.058/050.html> (sent by “kleeds4210@yahoo.com”, Jan. 17, 2002).

<sup>42</sup>E-mail from The Spamarchive, at <http://mellin.org/spamarchive/view.jsp?id=310> (added Jan. 4, 2003).

- **ThermoLift Weight Loss Product** (“Denita went from 340 pounds to 128 pounds in 18 months”)<sup>43</sup>
- **Vigoral Herbal Love Enhancers** (“100% Natural Products to stimulate your moments with that special someone”)<sup>44</sup>

And the list goes on. From this cornucopia of counterfeit claims, however, one clear champion emerges. The most popular and most representative spam subject line of 2003 – the penis enlargement pill.<sup>45</sup>

\* \* \* \* \*

**Get a Massive Penis Overnight**<sup>46</sup>

Want a BIG Penis? Experience the results you’ve always wanted with a MASSIVE scientific breakthrough.

Our Doctor-Approved Pill Will Actually Expand, Lengthen And Enlarge Your Penis.

WE GUARANTEE GENUINE LASTING RESULTS!  
 PINACLE PILLS WILL WORK FOR YOU 100%, OR YOU GET 100% OF YOUR MONEY BACK!

If YOU want to massively enlarge your penis and experience big gains in only weeks, this may be the most important email you’ll ever read. Here’s why.

Quiksilver Natural Labs has helped 1000’s of men cope with and conquer serious erectile dysfunction issues. These painful problems include small penis size and poor self-image, as well as lack of potency and premature ejaculation. To help these men our dedicated team of researchers has developed an amazing formula called Pinnacle. Quiksilver Natural Labs has carefully tested this unique new product so that it is fully doctor-approved. And, it is 100% guaranteed to work. It has been described as a true ‘miracle cure’, and we are

<sup>43</sup>E-mail from The Great Spam Archive, at <http://www.annexia.org/spam/messages/Junk26/014.html> (sent by “money-man@aol.com”, Jan. 24, 1998).

<sup>44</sup>E-mail from The Great Spam Archive, at <http://www.annexia.org/spam/messages/spam.064/053.html> (sent by “dev-ilz99@hotmail.com”, Jul. 11, 2002).

<sup>45</sup>See Brightmail Reports on Spam Trends of 2003, *supra* note 28.

<sup>46</sup>E-mail from The Spamarchive, at <http://mellin.org/spamarchive/view.jsp?id=6270> (added Jan. 12, 2003).



now offering Pinnacle in easy pill form to men everywhere. The Quiksilver Natural research team invites you now to experience this miracle for yourself.

### **Now You Can Forget Forever the Pain, Effort and Expense of Having a Large, Manly Penis!**

Imagine for a moment how you will feel. You'll radiate confidence and success whenever you enter a locker room, and other men will look at you with real envy. But the best part is when you reveal yourself in all your glory to the woman in your life. When she sees how massive and manly, how truly long and hard you are, she will surrender and give you everything you have always wanted.

The feeling of power is sensational, and the sex is unbelievable! As you drive your penis deep inside her she'll gasp as you dominate her. And the intense satisfaction you give her will be the BEST sex she has ever had. I promise you, she will not be able to keep her hands off you when you give her everything she needs from a man.

**YOU Are In Total Command!** Pinnacle will make you long-lasting and rock hard.

You will never worry or be concerned about losing your hard-on or reaching orgasm too fast. With Pinnacle these problems are completely eliminated.

### **How Pinnacle Works, and Exactly How it Will MASSIVELY ENLARGE YOUR PENIS**

On either side of your penis, you have two spongy areas called the corpa cavernosa. An erection happens when you become excited, and the natural flow of blood fills these erectile tissues. Pinnacle has been scientifically developed to expand these erectile tissues and make them much larger. As it does this the erectile tissues can hold more blood than ever before. The result? A MUCH larger penis in thickness and length, and a rock solid erection. And all you have to do to experience these massive results is take Pinnacle pills. That's it.

With Pinnacle, it all happens easily and gently in just a few weeks.

### **How BIG Can You Get?**

this with the added thickness you gain with Pinnacle, and you will fill her with exhilarating, exquisite sensations (some women say that thickness means everything!) It now becomes possible for you to reach her most sensitive area of all - the famous 'G spot' - giving her the sensations she needs and craves to have multiple orgasms. Think what this will do for your confidence and power of your lovemaking! At the same time you are satisfying her cravings with your large, manly penis, YOU are receiving more pleasure on your sensitive nerve endings than you can imagine. Once you reach this sexual height you'll never look back. It's awesome!

### **Is My Penis Growth PERMANENT? YES!**

Take Pinacle, grow to the perfect size for you, and you can even stop taking the pills. You are right where you want to be, and you can stay there forever! Remember, a penis larger than 9 may be too large for most women. But IF for some reason you need even more, it is possible for you to safely continue taking Pinacle.

The choice is up to you — [Order Pinacle Today!] — [CLICK HERE](#)

\* \* \* \* \*

Does Pinacle work? Joe Miksch, a journalist who ordered a month’s supply of Pinacle pills, reports his results: “Day one: No change. Day two: No change. Day three: No change. Days four through 30: See above.”<sup>47</sup>

Despite this lack of massive success, penis enlargement pills – and now, penis enlargement patches – are probably spammers’ signature subject. A critical evaluation of why regulatory action has failed to stop dietary supplement spam follows in Section IV.

#### D. Spam Promoting Medical Devices – “Sleep Angel”

The last broad category of health product spam is spam promoting medical devices. Indeed, the next chapter in the rich history of fraudulent medical devices is being written online.

“Sleep Angel” is a chinstrap which supposedly controls sleep apnea. Sleep Angel is a fraudulent medical device – the FDA database of approved medical devices did not identify Sleep Angel as a valid medical device,<sup>48</sup> and the Sleep Angel website no longer exists.<sup>49</sup> Yet the spam below is remarkably sophisticated – originally weighing in at 3,300 words – and instills fear through scientific sound bites linking apnea to many

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<sup>47</sup>Joe Miksch, [Penis Man: Can you really make it bigger by answering your spam?](http://www.newhavenadvocate.com/gbase/News/content.html?oid=oid:24050), New Haven Advocate, July 10, 2003, available at <http://www.newhavenadvocate.com/gbase/News/content.html?oid=oid:24050>.

<sup>48</sup>A search of the FDA’s Premarket Approvals (PMA) and Premarket Notifications (510(k)) databases returned no results for “Sleep Angel” as of February 26, 2004.

<sup>49</sup>Searches for “Sleep Angel” returned no commercial website results as of February 29, 2004.

fatal medical conditions. The salvation to the fatal consequences of snoring, is, of course, the Sleep Angel. Indeed, the concluding testimonial from Sleep Angel's inventor asserts that Sleep Angel "truly literally saved my life."

\* \* \* \* \*

**Do you suffer from sleep apnea? Relief is here.** <sup>50</sup>

ARE YOU SNORING YOURSELF TO DEATH?

Snoring is often a precursor of serious upper airway disorders such as OSA (the closing of the upper airway while asleep.) Some symptoms are.

Limb jerking, punching and kicking during sleep

Depression, reduction in motivation

ADHD symptoms (hyperactivity)

Morning headaches, bloodshot eyes

Multiple trips to the bathroom during sleep time

Heartburn (Acid Reflux)

Waking up very tired (feeling exhausted) and thirsty

Weight gain and love handles in men over 35

Memory problems

... In most cases, this sets the stage for snoring and the possible Development of Obstructive Sleep Apnea (OSA).

**SLEEP ANGEL PROVIDES RELIEF!**

Sleep Angel is a lightweight device that supports your jaw comfortably while you sleep, so it helps keep your mouth closed while you're sleeping. Sleep Angel actually helps you retrain the skin and tissue in your mouth and throat, so that they return to the size and shape they once were. The result is that, with continued use, Sleep Angel can help you help you stop snoring and get a better night's sleep ...

Sleep Angel can be worn by everyone in the family!

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<sup>50</sup>E-mail from The Spamarchive, at <http://mellin.org/spamarchive/view.jsp?id=6529> (added Jan. 17, 2003). Emphasis has been added throughout.

The SLEEP ANGEL is conveniently priced at just \$44.97 plus shipping and handling and comes with an unconditional 30-day money back guarantee.

CLICK HERE TO ORDER YOUR SLEEP ANGEL NOW!

<http://b.dlbnetwork.net/T/r.cfm?U=118442819&L=19877> Click Here

...In fact, results from a recent study indicate that one in three men and nearly one in five women who snore habitually suffer from some degree of OSA ... OSA sufferers never get a “good nights sleep” because repeated arousal’s deprive patients of REM (deep-sleep stage) leading to chronic daytime exhaustion and long-term cardiovascular stress...

It is also important to remember that when the immune system is compromised by a lack of oxygen, we are more susceptible to opportunistic bacteria, viral, and parasitic infections and colds, as well as flu.

*Oxygen deprivation can also lead to life-threatening disease, such as cancer. Cancer and most other infections or disease cannot live in an oxygen-rich environment.*

Scientific quotes about the links between oxygen deprivation caused by OSA, cancer, and heart attacks

The National Commission on Sleep Disorders Research estimates that *38,000 cardiovascular deaths*, due to sleep apnea, occur each year. . . .

[Lengthy discussion of sleep apnea and obstructive sleep apnea]

Twenty-four percent of adult men and nine percent of adult women are estimated to have some degree of OSA.

**[Testimonials]**

Dear Steve,

For the past few years I’ve been unable to sleep through the night —or for very long. I considered 4 hours of sound sleep a good night’s sleep. I was always tired, and figured that my memory loss & feeling weak came with age—at 43. My wife was beginning to complain about my snoring & jerking in the night . . . . I’d have an hour or two of uninterrupted sleep, then my body would cramp because of being unable to move. Sleep Angel changed all of that . . . . I can sleep as long as I want and feel life returning to me . . . . The materials used are perfect; it’s as comfortable as a well broken in T- shirt . . . . I don’t have to be afraid of going to bed anymore and I now know what a full night’s sleep feels like. Thank you Sleep Angel, Perry Vath - Pace, FL

[Other testimonials omitted]

### ***ADHD in Children***

CNN Headline News recently reported on a study that new research suggests *children who snore face nearly double the risk of being inattentive and hyperactive*, providing fresh evidence of an intriguing link between

sleep problems and *attention deficit disorders* . . . . Children who snore often are nearly twice as likely as other children to have attention and hyperactivity problems, found a new study by the University of Michigan Health System. . . .

***Depression and Insomnia in Women***

One of the main concerns with lack of sleep for women is depression contributed to lack of sleep . . . . This affects a woman's hormone level which will cause more sensitivity, mood swings, and irritability . . . . The American College of Cardiology found that 33 percent of 71,779 female nurses aged 40 to 65 who snored were more at risk of developing cardiovascular disease than those who did not snore.

***Love Handles and Fat Gain in Men***

Men who suffer with obstructive sleep apnea often gain weight in the abdomen due to the process of age . . . . That deficiency is associated with increased fat tissue and abdominal obesity, reduced muscle mass and strength, and reduced exercise capacity . . . .

***[Testimonial by Inventor of Sleep Angel]***

Hello! I'm Steve Brown . . . . Over a year ago, I began experiencing severe depression, irritability, excessive daytime sleepiness, and lack of concentration, forgetfulness, anxiety, and severe headaches. Little did I know it at the time that these were all symptoms of Obstructive Sleep Apnea (OSA.) . . . .

Several months ago, *I nearly died* one night in my sleep, from the progression of the Apnea symptoms. Later that day, I learned that death is not uncommon for those who go untreated . . . . *I was facing another night without sleep, and frankly didn't believe I would survive it. . .*

Some of my background is in engineering . . . . So, I went home and designed, and made, the device that would, later that night, prevent my sleep apnea from occurring. Simple and comfortable! I slept like a baby that night.

Since then, I have been fine-tuning this sleep miracle . . . My depression and anxiety have disappeared, I'm thinking more clearly. I have no more headaches, and I'm full of energy!!! I feel like I'm 17 again!!! I really do! All because of my little Sleep Angel!!! *This product truly literally saved my life.*

CLICK HERE TO ORDER YOUR SLEEP ANGEL NOW

\* \* \* \* \*

"Sleep Angel" shows the consumer confusion caused by spam promoting fraudulent medical devices. On

Sleepquest.com’s sleep apnea forum, dozens of messages highlight a lively discussion about Sleep Angel.<sup>51</sup> While a few users claimed that Sleep Angel reduced their snoring,<sup>52</sup> most users asserted that Sleep Angel did not help them sleep: “I think it is crap.... I couldn’t sleep with it, it choked [sic] me, and was just plain uncomfortable . . . . I think they are cheats and frauds, and I wish there was some way I could expose them throughout the whole world.”<sup>53</sup> Indeed, many users reported that the Sleep Angel company did not honor its 30 day guarantee, give refunds, or answer phone calls for customer service.<sup>54</sup> One user reported that the company changed its name because it was banned for fraud in several states.<sup>55</sup> Another cried out for legal relief: “I wish we could get a class action suit started against these rip-off artists.”<sup>56</sup>

#### **IV. The Food and Drug Administration’s Actions Against Health Product Spam**

What legal relief can be taken to protect consumers and stop health product spam? This section evaluates the FDA’s role in regulating the e-mail advertising of prescription drugs, fraudulent drugs, dietary supplements, and medical devices. While FDA has clear statutory authority to regulate health product spam, FDA’s inadequate enforcement resources have blunted the impact of its actions to protect consumers from deceptive and misleading health product e-mails.

##### **A. Spam Promoting Prescription Drugs**

Prescription drug spam such as “21 CENTURY MIRACLE PRESCRIPTIONS” above often lures consumers to Internet pharmacies which claim to sell prescription drugs. This is a big and growing business – Congress

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<sup>51</sup>Sleep Apnea Forum, at <http://www.sleepquest.com/cgi-bin/forum/SleepApnea/index.html>

<sup>52</sup>See “Re: Sleep Angel” at <http://www.sleepquest.com/cgi-bin/forum/SleepApnea/messages/618.html> (Oct. 7, 2003).

<sup>53</sup>“Re: Sleep Angel” at <http://www.sleepquest.com/cgi-bin/forum/SleepApnea/messages/636.html> (Oct. 21, 2003).

<sup>54</sup>See, e.g., <http://www.sleepquest.com/cgi-bin/forum/SleepApnea/messages/643.html> (Oct. 21, 2003).

<sup>55</sup>Id. Other industry watchers note the “Sleep Angel” brand has vanished and has re-emerged without explanation as “Sleep Wizard” and “Snoring Stopper.” “Put an End to Snoring Newsletter” at <http://www.putanendtosnoring.com/Newsletters/12-03.htm> (Dec. 2003).

<sup>56</sup>See “Re: Sleep Angel” at <http://www.sleepquest.com/cgi-bin/forum/SleepApnea/messages/676.html> (Oct. 29, 2003).

estimates that 320 million people will access Internet pharmacy sites by 2005.<sup>57</sup>

Prescription Drug Spam Leads to “Rogue” Pharmacies. Although lawful Internet pharmacies sell bona fide prescription drugs to consumers, prescription drug spam often lures unsuspecting consumers to “rogue” pharmacies which sell counterfeit drugs that may be hazardous to health. A 2000 study by FDA’s Office of Criminal Investigation found 300 to 400 Internet sites selling prescription drugs to consumers, with approximately half located in the U.S. and half in foreign countries.<sup>58</sup> FDA warns that these pharmacies may dispense expired, subpotent, contaminated, or counterfeit products; the wrong or contraindicated products; an incorrect dose; or medication unaccompanied by adequate directions for use.<sup>59</sup> As of March 2003, FDA received over 300 messages a day in its Reporting Unlawful Sales of Medical Products on the Internet system.<sup>60</sup>

Prescription Drug Spam Can Kill People. Spam like “21 CENTURY MIRACLE PRESCRIPTIONS” that promotes cheap Viagra and leads to rogue pharmacies can be a matter of life and death. In 1999, a chronically depressed man died after consuming controlled substances bought from an overseas pharmacy not requiring a prescription.<sup>61</sup> Another man died of a heart attack after purchasing Viagra from an online pharmacy which required no prescription.<sup>62</sup> In 2001, two California men died after complications from prescriptions filled on the Internet.<sup>63</sup> As spam luring consumers to rogue pharmacies increases, the number of deaths from these rogue pharmacies will also increase.

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<sup>57</sup>Point, Click, Self-Medicare: A Review of Consumer Protection Safeguards on Internet Pharmacy Sites: Hearing Before the H.R. Comm. on C  
108th Cong. (2003) (statement of Rep. Chris Bell).

<sup>58</sup>South Florida’s Access to Affordable Prescription Drugs: Costs and Benefits of Alternative Solutions: Hearing Before the Subcomm. on Over  
108th Cong. (2003) (statement of John Taylor, Associate Commissioner for Regulatory Affairs at FDA).

<sup>59</sup>Id.

<sup>60</sup>Id.

<sup>61</sup>Continuing Concerns over Imported Pharmaceuticals: Hearings Before the Subcomm. on Oversight and Investigations of the H.R. Comm. on  
107th Cong. (2001) (testimony of Edwin and Helen Rode).

<sup>62</sup>R.J. Ignelzi, Risky Prescription: Online Drug Buyers Gamble With More Than Credit Cards, San Diego Union-Tribune, Aug. 6, 2003.

<sup>63</sup>David Hasemeyer, Easy Access to Drugs is Becoming Increasingly Deadly, San Diego Union-Tribune, Dec. 20, 2003.

Prescription Drug Spam Violates FDA Advertising Regulations. “21 CENTURY MIRACLE PRESCRIPTIONS”, like most prescription drug spam, violates FDA prescription drug advertising regulations in two ways. First, such spam promotes prescription drugs while omitting the risks associated with the drug. Knowing that taking Viagra increased the risk of heart attacks might have saved the above man’s life. Second, such spam often touts a prescription drug as a “cure-all” and makes claims which deviate from FDA-approved claims and the official product’s labeling. Thus, this spam violates both the misbranded drug provisions of 21 U.S.C. § 352(n) and FDA’s regulations requiring inclusion of side effects and contraindications at 21 C.F.R. § 202.1(e).

Prescription Drug Spam Helps Violate the Prescription Requirement. Federal law requires that prescription drugs be issued only with a valid prescription.<sup>64</sup> Case law defining a prescription requires that the prescription be issued “to a patient . . . in the course of professional practice only”<sup>65</sup> and within a valid doctor-patient relationship.<sup>66</sup> Internet pharmacies violate the law if they introduce prescription drugs issued without a valid prescription into interstate commerce.<sup>67</sup> These rogue pharmacies are then liable for both civil and criminal penalties.<sup>68</sup>

Language like “IMMEDIATE PRESCRIPTION DISPENSING IF THE PHYSICIAN does not approve you. NO CHARGE.” in spam like “21 CENTURY MIRACLE PRESCRIPTIONS” strongly suggests that the prescription requirement on rogue pharmacy sites is an empty fiction.<sup>69</sup> Indeed, the promise of prescription drugs without the need to go to a doctor is what lures many consumers to rogue pharmacies. These

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<sup>64</sup>21 U.S.C. § 353(b)(1) (2004).

<sup>65</sup>*Jin Fuey Moy v. United States*, 254 U.S. 189, 194 (1920).

<sup>66</sup>*Brown v. United States*, 250 F.2d 745, 747 (5th Cir. 1958).

<sup>67</sup>21 U.S.C. § 331(a) (2004).

<sup>68</sup>21 U.S.C. § 333(a) (2004).

<sup>69</sup>“21 CENTURY MIRACLE PRESCRIPTIONS”, supra note 33.



rubber-stamp pharmacies circumvent the prescription requirement by having users fill out a simple online questionnaire instead of seeing an actual doctor.<sup>70</sup> Unscrupulous doctors play their part by approving any and all prescription requests. According to Dr. Hazem Chehabi, President of the California Medical Board, “Rather than see three patients in one hour, a doctor can sit on the Internet and prescribe to 600 people in an hour and make a lot more money.”<sup>71</sup> Prescribing 600 people in an hour perverts the doctor-patient relationship and violates the legal standard for dispensing prescription drugs.

Prescription Drug Spam Promotes Counterfeit Drugs. Spam often leads to rogue pharmacies which – mildly stated – do not follow good manufacturing practices assuring the quality of prescription drugs. For example, one rogue pharmacy sold injections of human growth hormone that was actually insulin; another rogue pharmacy sold vials of cancer medication that was actually tap water.<sup>72</sup> The FDA can prevent such shocking scenarios by invoking its authority under 21 U.S.C. § 355 to prevent unapproved foreign versions of U.S. drugs from being introduced into U.S. interstate commerce. Indeed, the FDA has increased the number of active counterfeit drug investigations from 6 cases in 2000 to 22 cases in 2003.<sup>73</sup> However, the FDA admits that it “does not have the legal authority or resources to assure the safety and efficacy of drugs purchased outside our domestic drug distribution system, or from unregulated Internet sites that are not run by pharmacies licensed and regulated by U.S. states.”<sup>74</sup> In short, while FDA can shut down U.S.-based rogue pharmacies, it is largely powerless to stop the flow of counterfeit prescription drugs from foreign rogue pharmacies. Is

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<sup>70</sup>See South Florida’s Access to Affordable Prescription Drugs, supra note 58 (statement of John Taylor, Associate Commissioner for Regulatory Affairs at FDA); see also Point, Click, Self-Medicare, supra note 57 (screenshots of sample online prescription questionnaires, in prepared statement of William Hubbard, Associate Commissioner for Policy, Planning, and Legislation for Dept. of Health and Human Services).

<sup>71</sup>Hasemeyer, supra note 63.

<sup>72</sup>A System Overwhelmed: The Avalanche of Imported, Counterfeit, and Unapproved Drugs into the U.S.: Hearings Before the Subcomm. on C  
108th Cong. (2003) (statement of Robert Penezik, Assistant Statewide Prosecutor, Office of Statewide Prosecution, State of Florida); see also Point, Click, Self-Medicare supra note 57 (prepared statement of Federal Trade Commission discussing specific fraudulent drug claims resulting in enforcement actions against manufacturers).

<sup>73</sup>Food and Drug Administration, Combating Counterfeit Drugs at 1-2 (Feb. 18, 2004), available at <http://www.fda.gov/oc/initiatives/counterfeit/02.04.pdf>.

<sup>74</sup>Id. at v.

there then nothing that can be done to stop prescription drug spam and counterfeit prescription drugs?

Direct Regulation of Prescription Drug Spam Will Not Work. The FDA should enforce its authority over prescription drug spam to require listing side effects and contraindications as well as the benefits of drugs. Anonymous spammers hired by rogue pharmacies, however, are not likely to comply. The better solution to stopping prescription drug spam is for FDA to attack the source and sponsor of the prescription drug spam – the rogue pharmacies themselves.

Stopping Prescription Drug Spam by Stopping Rogue Pharmacies – State, FDA, and DEA Enforcement Actions.

Both federal and state agencies can seek injunctions against rogue pharmacies to shut down their operations or to prevent the shipment of fraudulent prescription drugs into their jurisdiction. As of December 2003, 28 states have passed laws regulating Internet pharmacies and prescription practices; the most stringent, such as California and Nevada, require doctors perform a physical examination before issuing a prescription.<sup>75</sup> However, state injunctions against rogue pharmacies breaking their laws may be limited to only that state's jurisdiction. While various proposals to allow national scope for state injunctions against rogue pharmacies are being discussed,<sup>76</sup> currently federal enforcement actions offer the widest impact against rogue pharmacies.

Indeed, FDA has been active in preventing fraudulent prescription drug sales by domestic and foreign Internet pharmacies. As of March 2003, FDA had sent 55 warning letters to domestic Internet pharmacies and 137 warning letters to foreign Internet pharmacies.<sup>77</sup> About 20% of the recipients complied with the request to discontinue illegal dispensing practices.<sup>78</sup> However, FDA has stated that effective action against foreign

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<sup>75</sup>See Hasemeyer, *supra* note 63; see also John Michael Ward, *Online Pharmaceutical Regulation: An Avenue to a Safer World*, 24 J. Legal Med. 77, 90-94 (2003) (discussing the differences in Illinois, Indiana, and Nevada's regulation of Internet pharmacies).

<sup>76</sup>See Ward, *supra* note 75 at 103-04.

<sup>77</sup>*South Florida's Access to Affordable Prescription Drugs*, *supra* note 58 (statement of John Taylor, Associate Commissioner for Regulatory Affairs at FDA).

<sup>78</sup>*Comparative Pricing of Prescription Drugs Sold in the U.S. and Canada and the Effects on U.S. Customers: Hearings Before the Subcomm. 107th Cong. (2001)* (prepared statement of William Hubbard, Associate Commissioner for Policy, Planning, and Legislation for Dept. of Health and Human Services).

pharmacies depends on foreign governments' willingness to cooperate with FDA – cooperation that cannot be taken for granted.<sup>79</sup>

In conjunction with warning letters, FDA had also launched 370 Internet drug criminal investigations, with 90 involving domestic Internet pharmacies.<sup>80</sup> These investigations resulted in 150 Internet-related drug arrests, with 60 involving Internet pharmacies; these arrests resulted in 92 Internet-related drug convictions, with 26 convictions involving Internet pharmacies.<sup>81</sup> Furthermore, 90 websites were under active review for possible regulatory or civil action.<sup>82</sup>

Of course, FDA is not the sole federal agency taking enforcement actions against rogue pharmacies sending out prescription drug spam. FTC enforcement actions against rogue pharmacies are evaluated in Section V. Furthermore, the Drug Enforcement Administration (“DEA”) has targeted physicians who rubber-stamp Internet pharmacy prescriptions. In one sting, the DEA undercover agent went to an Internet pharmacy to request a weight loss prescription. On the online questionnaire, the agent listed a body weight and concurrent medications that would have been fatal in combination with the weight loss prescription. When the physician still prescribed the weight loss drug, the DEA seized the pharmacy's records – finding the pharmacy's “patients” included an 89-pound woman addicted to weight loss amphetamines – and suspended the physician's license.<sup>83</sup> Since 2001, similar stings have resulted in the suspension of a dozen physicians in California alone.<sup>84</sup> Enforcement actions by the FDA and DEA, then, are having some limited effect on rogue pharmacies, and thus also on the prescription drug spam which lures consumers to the pharmacies.

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#### Protecting Consumers Through Education About Prescription Drug Spam Leading to Rogue Pharmacies. FDA

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<sup>79</sup>Id.

<sup>80</sup>See Point, Click, Self-Medicare, supra note 57 (prepared statement of William Hubbard, Associate Commissioner for Policy, Planning, and Legislation for Dept. of Health and Human Services).

<sup>81</sup>Id.

<sup>82</sup>Id.

<sup>83</sup>See Hasemeyer, supra note 63.

<sup>84</sup>See id.

has also attempted to stop the harms caused by prescription drug spam by educating consumers about the potential dangers of buying counterfeit drugs from online pharmacies. On its “Buying Medicines and Medical Products Online” website, FDA offers comprehensive advice on topics including, “Buying Prescription Drugs Online: A Consumer Safety Guide”, “What You Should Know About Buying Foreign Medicines”, and “How to Spot Health Fraud.”<sup>85</sup> The FDA website also allows consumers to report unlawful sales of medical products on the Internet.<sup>86</sup> As of March 2003, consumers were using this system to report over 300 suspected rogue pharmacies a day.<sup>87</sup>

Protecting Consumers Through Authentication of Bona Fide Prescription Drugs. FDA plans to protect consumers by tagging bona fide prescription drugs through “track and trace” and product authentication technologies.<sup>88</sup> These anti-counterfeiting technologies will guarantee the pedigree of Internet prescription drugs, and the absence of such authentication will signal the consumer that the prescription drug is counterfeit and may be hazardous to health. The FDA predicts that such technologies will be feasible for use by 2007.<sup>89</sup>

Protecting Consumers Through the VIPPS Certification Standard for Internet Pharmacies. Beyond FDA, the National Association of Boards of Pharmacy has also stepped in to help consumers by providing benchmarks for reliable Internet pharmacies. The Verified Internet Pharmacy Prescription Sites (“VIPPS”) seal is displayed on an approved pharmacy’s website and provides notice to consumers that the pharmacy is reputable and reliable.<sup>90</sup> The VIPPS certification requirements include proper pharmacy licensing, a phys-

<sup>85</sup>See Food and Drug Administration, “Buying Medicines and Medical Products Online”, at <http://www.fda.gov/oc/buyonline/default.htm> (last visited Apr. 7, 2004).

<sup>86</sup>See Food and Drug Administration, “Reporting Unlawful Sales of Products on the Internet”, at <http://www.fda.gov/oc/buyonline/buyonlineform.htm> (last visited Apr. 7, 2004).

<sup>87</sup>See South Florida’s Access to Affordable Prescription Drugs, *supra* note 58 (statement of John Taylor, Associate Commissioner for Regulatory Affairs at FDA).

<sup>88</sup>Food and Drug Administration, Combating Counterfeit Drugs, *supra* note 73, at i-iii.

<sup>89</sup>*Id.*

<sup>90</sup>See Point, Click, Self-Medicare, *supra* note 57 (prepared statement of National Association of Boards of Pharmacy, discussing the establishment of VIPPS and the specific standard requirements).

ical examination before prescriptions are dispensed, and procedures to ensure patient privacy.<sup>91</sup> Currently, only 14 Internet pharmacies have been VIPPS certified.<sup>92</sup> This strongly suggests that the hundreds if not thousands of other Internet pharmacies in existence fail to meet even the commonsense VIPPS standards – a very troubling thought.

#### The Fight Against Prescription Drug Spam and Rogue Pharmacies Requires Cooperation Between FDA, FTC, State Agencies

This discussion shows that fighting prescription drug spam and rogue pharmacies requires a coordinated effort between federal, state, and professional medical associations. In April 1999, such a broad working group was created, with the FDA, FTC, the Department of Justice, the DEA, and other federal and state agencies meeting quarterly to share information and discuss interagency coordination.<sup>93</sup> Furthermore, the FDA meets regularly with the National Association of Boards of Pharmacy and the Federation of State Medical Boards to discuss how issues relating to online drug sales should be addressed and provide a forum for proposed regulations.<sup>94</sup> The FDA also works together with state boards of pharmacy to send concurrent warning letters to Internet pharmacies that they are violating both federal and state law.<sup>95</sup>

Domestic Coordination Alone is Not Enough – FDA’s Weak Foreign Enforcement Powers. Prescription drug spam is often sent by spammers who lure unsuspecting consumers to rogue pharmacies located in foreign jurisdictions. Because more than half of rogue pharmacies may be located outside the U.S.,<sup>96</sup> effective action

<sup>91</sup>Id.

<sup>92</sup>See National Association of Boards of Pharmacy, “VIPPS Database Search Results” at <http://www.nabp.net/vipps/consumer/listall.asp> (last visited Apr. 7, 2004).

<sup>93</sup>See Point, Click, Self-Medicare, supra note 57 (prepared statement of Howard Beales, Director of the Bureau of Consumer Protection of the Federal Trade Commission).

<sup>94</sup>See Point, Click, Self-Medicare, supra note 57 (prepared statement of William Hubbard, Associate Commissioner for Policy, Planning, and Legislation for Dept. of Health and Human Services).

<sup>95</sup>See id. (discussion of FDA’s joint efforts with the Arkansas State Board of Pharmacy in sending warning letters to Rx Depot, a storefront Internet pharmacy).

<sup>96</sup>See South Florida’s Access to Affordable Prescription Drugs, supra note 58 (statement of John Taylor, Associate Commissioner for Regulatory Affairs at FDA).

against the sources of counterfeit prescription drugs requires international cooperation. However, FDA has admitted that it lacks the legal authority and resources to police foreign drug imports.<sup>97</sup> While FDA intends to work with the World Health Organization, Interpol, and other international health and law enforcement organizations,<sup>98</sup> FDA projects that widespread international collaboration against foreign counterfeit drugs will not be available until at least 2007.<sup>99</sup>

Counterfeit Prescription Drug Spam Will Persist for the Foreseeable Future. Prescription drug spam is dangerous because it lures consumers into buying counterfeit drugs from untrustworthy Internet pharmacies with rubber-stamp prescription practices. The ultimate solution is to shut down the source and sponsor of prescription drug spam, the rogue Internet pharmacies. While FDA has effectively coordinated its enforcement efforts against domestic pharmacies with other federal, state, and professional medical associations, FDA is currently powerless to control the increasing flow of counterfeit drugs from foreign Internet pharmacies. Thus, it is likely that the problem of counterfeit prescription drug spam will get worse before it gets better.

#### B. Spam Promoting Fraudulent Drugs

While prescription drug spam promotes approved drugs of dubious quality, fraudulent drug spam promotes the miraculous qualities of drugs which have not been approved by FDA. This discussion focuses on the ongoing regulatory response to noni juice as a case study for FDA efforts against fraudulent drug spam as a whole. Please recall from Section III: “Noni juice considered the greatest health discovery since DNA . . . None of these people - not at any age - ever suffer from arthritis, bursitis or rheumatism. Serious and often

<sup>97</sup>See Food and Drug Administration, Combating Counterfeit Drugs, supra note 73 at iv-v.

<sup>98</sup>Id.

<sup>99</sup>See id. at 31.

fatal diseases such as diabetes, cancer, heart attacks, strokes and Parkinson's are virtually unknown."<sup>100</sup>

Why Noni Juice, And Fraudulent Drug Spam Claims Generally, Are Illegal. These noni juice claims are obviously illegal. First, noni juice is classified as a drug because the claims clearly tout the juice's beneficial uses in the diagnosis, cure, mitigation, treatment, or prevention of diseases.<sup>101</sup> Noni juice could generously be classified as a "new drug", because its efficacy is not generally recognized "among experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs."<sup>102</sup> However, FDA has no information that noni juice is generally recognized as safe and effective for the conditions above.<sup>103</sup> Therefore, spam selling noni juice violates the requirement that all new drugs be approved by FDA before being introduced into interstate commerce.<sup>104</sup>

Besides making drug claims, these noni juice claims are also simply false. Therefore, marketing noni juice is also illegal under the misbranding provisions of the Federal Food, Drug, and Cosmetic Act ("FDCA").<sup>105</sup> Given this track record for veracity, it is likely that much of the noni juice sold is not really noni juice at all, which would incur further liability as an adulterated drug.<sup>106</sup> Indeed, one commercial noni juice website warns that its competitors "create . . . hype with false claims" and "sell a product that is as little as 11% noni juice."<sup>107</sup> The same website, of course, is quick to note that its product is nothing but "100% Pure Tahitian Noni Juice with no additives, preservatives, flavors, colors, or any added water."<sup>108</sup>

If noni juice is an illegal fraudulent drug, why are there still dozens of commercial websites selling noni juice today? The following discussion evaluates the limited impact of FDA, state, and international regulatory

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<sup>100</sup>See "NONI JUICE CURE?", *supra* note 35.

<sup>101</sup>21 U.S.C. § 321(g)(1) (2004).

<sup>102</sup>21 U.S.C. § 321(p)(1) (2004).

<sup>103</sup>FDA states it lacks information about the purported curative effects of noni juice in its many warning letters to noni juice manufacturers. See, e.g., Letter from FDA to Hawaiian Island Noni of 7/31/02, available at <http://www.fda.gov/cder/warn/cyber/2002/CFSANhawaiian.htm> (last visited Apr. 7, 2004).

<sup>104</sup>21 U.S.C. § 355(a) (2004).

<sup>105</sup>21 U.S.C. §§ 331(a)-(c), 352(a) (2004).

<sup>106</sup>21 U.S.C. § 351(c)-(d) (2004) (liability for misrepresenting or reducing the strength and quality of a drug).

<sup>107</sup>Noni-Juice-Plus, Noni Juice "Hype", at <http://www.noni-juice-plus.com/noni-juice-hype.html> (last visited Apr. 7, 2004).

<sup>108</sup>Id.

action on the thriving noni juice industry.

Noni Juice Case Study: FDA Warning Letters, Import Refusals, and Inspections. When FDA finds fraudulent drug claims, it writes a warning letter to manufacturers, marketers, and distributors of the drug. FDA has sent several warning letters to U.S. and international distributors of noni juice warning them against making claims that noni juice can cure cancer and arthritis.<sup>109</sup> FDA inspectors have also refused imports of adulterated noni pulp from Panama<sup>110</sup> and misbranded noni juice from Canada.<sup>111</sup>

FDA inspections have also forced some noni juice manufacturers to voluntarily correct their practices. In May 2002, FDA inspected Fresh Vitamins, a noni juice manufacturer which marketed its juice for conditions ranging from immune system disorders to arthritis, malaria, and alcohol addiction. Following the inspection, the firm's president stated that he had removed impermissible claims from his website and that "he was educating himself on FDA policy."<sup>112</sup>

Contrast: The EU's More Aggressive Responses to Noni Juice. The U.S. FDA's warning letters and inspections have been less aggressive than EU enforcement actions against fraudulent noni juice. In 2000, the German equivalent of the FDA seized noni juice being exhibited at a trade show on the grounds that it was a "novel food" which was illegal to advertise or sell.<sup>113</sup> Finland imposed a ban on the import, export, sale, and serving of noni juice from 1998-2003, only lifting the ban on the condition that no marketing claims

<sup>109</sup>See, e.g., Letter from FDA to Hawaiian Island Noni of 7/31/02, supra note 103; Letter from FDA to Noni Juice Sales of 5/6/02, available at <http://www.fda.gov/cder/warn/cyber/2002/CFSANnoni juice.htm> (letter to Massachusetts distributor of noni juice); Letter from FDA to Bedessee Sporting Goods of 9/15/00, available at <http://www.fda.gov/cder/warn/cyber/sep2000/cyber025.pdf> (letter to Canadian distributor of noni juice).

<sup>110</sup>A Panamanian shipment of noni pulp was blocked on Feb. 4, 2004 because of adulteration. See FDA Refusal Actions record at [http://www.fda.gov/ora/oasis/2/ora\\_oasis.i.21.html](http://www.fda.gov/ora/oasis/2/ora_oasis.i.21.html).

<sup>111</sup>A Canadian shipment of noni juice bottles was blocked on Apr. 15, 2003 because of misbranding. See FDA Refusal Actions record at [http://www.fda.gov/ora/oasis/4/ora\\_oasis.i.22.html](http://www.fda.gov/ora/oasis/4/ora_oasis.i.22.html).

<sup>112</sup>Food and Drug Administration, Dietary Supplement Enforcement Report (2002), available at <http://www.fda.gov/oc/nutritioninitiative/report.html>.

<sup>113</sup>For a lively discussion denouncing the German FDA's seizure of noni juice, see <http://www.iahf.com/europe/noni juice.html> (last visited Apr. 7, 2004).



could be made about noni juice's potential to prevent, treat, or cure disease.<sup>114</sup> In short, the global reach of fraudulent drug spam provokes a global regulatory response, and it is unclear why the U.S. FDA, at least with regard to noni juice, should lag in enforcement efforts.

Noni Juice Case Study: State Settlements with Noni Juice Manufacturers. States have also been effective in preventing noni juice manufacturers from making fraudulent drug claims through websites and e-mail advertising. On August 26, 1998, the Attorneys General of Arizona, California, New Jersey, and Texas announced a multi-state settlement with Morinda, Inc., a Utah company which operates one of the leading commercial noni juice websites, TahitianNoni.com.<sup>115</sup> Morinda agreed to stop making claims that its "Tahitian Noni" juice could treat, cure or prevent disease until the juice was approved as a new drug by the FDA.<sup>116</sup> Morinda also agreed to not make any other health claims about Tahitian Noni unless the company can substantiate the claim by reliable scientific evidence.<sup>117</sup> The settlement also forbid the use of testimonials which implied results that were not the typical or ordinary experience of consumers in actual conditions of use.<sup>118</sup> Finally, Morinda agreed to pay refunds to consumers who requested refunds in writing, and to pay \$100,000 for investigative costs.<sup>119</sup> Despite complying with the terms of this settlement, however, Morinda's Tahitian Noni website continues to run a booming business, marketing noni juice to 30 countries in 4 continents.<sup>120</sup>

Noni Juice Spam Resulted in the First Private Damages Under State Anti-Spam Laws. Noni juice spam has

<sup>114</sup>Finland Lifts Noni Juice Ban, Beverage Daily, at <http://www.beveragedaily.com/news/news-NG.asp?id=11993> (Nov. 8, 2003).

<sup>115</sup>Morinda, Inc.'s noni juice website is Tahitian Noni, at <http://www.tahitiannoni.com/> (last visited Apr. 7, 2004). Curiously enough, Morinda, Inc. also operates Stephen's International, a website devoted to promoting hot chocolate beverages. See <http://www.stephensintl.com/index.php> (last visited Apr. 7, 2004).

<sup>116</sup>Attorney Generals Curb Claims for Tahitian Noni, Quackwatch, at <http://www.quackwatch.org/04ConsumerEducation/News/noni.html> (last revised Sep. 12, 2002).

<sup>117</sup>Id.

<sup>118</sup>Id.

<sup>119</sup>Id.

<sup>120</sup>See Tahitian Noni website, supra note 115.

the dubious honor of resulting in the first settlement ever paid by spammers to their victims. In 1998, a freelance writer named Bruce Miller took advantage of Washington state's new anti-spam law and sent a "demand for damages" letter to a spammer who had e-mailed noni juice messages to Miller without his consent.<sup>121</sup> Both the spammer and the noni juice distributor who had commissioned the spam subsequently settled with Miller for \$200.<sup>122</sup> Section VII further discusses the impact of state anti-spam laws against health product spam.

Noni Juice: Despite Regulation, A Thriving Industry. Despite the numerous federal and state enforcement actions targeting the fraudulent marketing of noni juice as a drug, noni juice remains a thriving industry. Dozens of commercial websites are currently dedicated to selling noni.<sup>123</sup> The Tahitian Noni website alone boasts that its January 2004 sales were \$4 million higher than January 2003.<sup>124</sup> While the state settlement prevented Tahitian Noni from making claims to cure disease, the website still claims that noni juice "supports the immune system's natural ability to fight disease and infection", "is a superior energy antioxidant" that "increases energy levels", and "helps you absorb more nutrients at the cellular level."<sup>125</sup> Because these statements no longer claim to cure disease, noni juice is no longer classified as a drug. Instead, noni juice has joined the burgeoning category of health products that purport to affect the structure and function of the body – the category of dietary supplements.

### C. Spam Promoting Dietary Supplements

<sup>121</sup>Janet Kornblum, Settlement in First Anti-Spam Law, CNET News, available at <http://news.com.com/2100-1023-213430.html> (July 16, 1998).

<sup>122</sup>Id.

<sup>123</sup>See supra note 36.

<sup>124</sup>Press Release, Tahitian Noni International, Tahitian Noni International January's Sales are \$4 Million Higher and Continue Record-Breaking Pace, available at [http://www.tahitiannoni.com/us/company/press/pr\\_january\\_sales.htm](http://www.tahitiannoni.com/us/company/press/pr_january_sales.htm) (Feb. 10, 2004).

<sup>125</sup>Tahitian Noni International, Tahitian Noni Juice: What Does It Do For Me?, at [http://www.tahitiannoni.com/us/tnj/what\\_index.htm](http://www.tahitiannoni.com/us/tnj/what_index.htm) (last visited Apr. 7, 2004).

The Rise of Dietary Supplements and Dietary Supplement Spam. In 2000, dietary supplement sales reached \$17.1 billion and were projected to grow at a rate of more than 10% a year.<sup>126</sup> 158 million consumers use dietary supplements.<sup>127</sup> These consumers use dietary supplements to promote general feelings of health and well-being, to lose weight, for “medicinal” purposes such as preventing the common cold, and for many other reasons. The actual effect of these dietary supplements is often scientifically unsubstantiated, which opens the door for fraudulent dietary supplement spam.

Riding on the growth of the dietary supplement industry, dietary supplement spam – including penis enlargement pills, herbal aphrodisiacs, and miracle weight loss fat burners – is the most prevalent form of health product spam that afflicts American consumers today. Many of these dietary supplement claims are false. In the weight loss industry, for example, the FTC studied 300 weight loss advertisements from sources including spam and Internet websites disseminated in 2001. The FTC found that nearly 40% of the ads made at least one representation that almost certainly was false and that 55% of the ads made at least one representation that was very likely to be false or, at the very least, lacked adequate substantiation.<sup>128</sup> The steady rise of such crassly fraudulent dietary supplement spam is a consequence of FDA’s limited authority to regulate dietary supplements in contrast to FDA’s more extensive authority over drugs.

Statutes Regulating Dietary Supplement Claims – A Framework Inviting Abuse? The 1994 Dietary Supplement Health Education Act created the new regulatory class of dietary supplements. A dietary supplement is defined as a product intended to supplement the diet that contains one or more of the following ingredients: a vitamin, a mineral, an herb, an amino acid, or a dietary substance for use by man to supplement

<sup>126</sup>See Food and Drug Administration, Dietary Supplement Enforcement Report, *supra* note 112.

<sup>127</sup>*Id.*

<sup>128</sup>Federal Trade Commission, Weight-Loss Advertising: An Analysis of Current Trends (2002), available at <http://www.ftc.gov/bcp/reports/weightloss.pdf>.

the diet by increasing the total dietary intake.<sup>129</sup> Dietary supplements can be marketed with four distinct types of claims. First, dietary supplements can claim a benefit related to a classical nutrient deficiency disease and disclose the prevalence of such disease in the United States.<sup>130</sup> Second, dietary supplements can describe the role of a nutrient or dietary ingredient intended to affect the structure or function in humans.<sup>131</sup> Third, dietary supplements can characterize the documented mechanism by which a nutrient or dietary ingredient acts to maintain such structure or function.<sup>132</sup> Fourth, dietary supplements can describe general well-being from consumption of a nutrient or dietary ingredient.<sup>133</sup> Furthermore, all dietary supplement manufacturers must have some substantiation that the statements are truthful and not misleading, and the statement must contain the following disclaimer: “This statement has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease.”<sup>134</sup>

Penis Enlargement and the Troubling Expansion of Dietary Supplement Claims. Dietary supplement spam pushes the four permissible categories of dietary supplement claims to their breaking points. Spam promoting “Celtic Sea Algae” from Okinawa, Japan relies on “general well-being” statements (“These people just don’t get sick with the disease we face”) from the consumption of coral calcium.<sup>135</sup> Pinnacle Penis Enlargement Pills make gross “structure/function” claims (“Get a Massive Penis Overnight”) by describing how Pinnacle expands the corpora cavernosa tissues on the sides of the penis.<sup>136</sup> How can FDA help consumers distinguish between legitimate and illegitimate dietary supplement claims?

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<sup>129</sup>21 U.S.C. § 321(ff)(1) (2004).

<sup>130</sup>21 U.S.C. § 343(r)(6)(A) (2004).

<sup>131</sup>Id.

<sup>132</sup>Id.

<sup>133</sup>Id.

<sup>134</sup>21 U.S.C. § 343(r)(6)(B)-(C) (2004).

<sup>135</sup>See supra note 38.

<sup>136</sup>See supra note 46.

FDA Regulation of Inherently Misleading vs. Potentially Misleading Dietary Supplement Claims in Spam. Dietary supplement claims for products like Pinnacle pills are so spurious that they could be classified as “inherently misleading” and be banned entirely.<sup>137</sup> However, claims for products such as “Celtic Sea Algae” are probably only “potentially misleading”, because the consumption of calcium has a limited effect on maintaining good health. Therefore, dietary supplement spam relying on “general well-being” statements may resist regulation if accompanied by an appropriately drafted disclaimer. However, the vast majority of dietary supplement spam fails to pass even this generous test; most dietary supplement spam lacks both an FDA disclaimer and substantiation that the claims made are truthful. Thus, most dietary supplement spam would still fall under the scope of FDA regulatory authority and its associated penalties.

Aggressive (But Inadequate) FDA Enforcement Actions Against Dietary Supplement Manufacturers. FDA regulation of dietary supplements has not been limited to stopping misleading dietary supplement claims. In 2002, FDA budgeted \$500,000 towards dietary supplement enforcement, which included passive activities such as publicity and warning letters to the more aggressive actions below:

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<sup>137</sup>See Pearson v. Shalala, 130 F.Supp.2d 105, 113 (D.D.C. 2001) (court acknowledged that inherently misleading speech could be banned but allowed potentially misleading folic acid claims to be disseminated with an FDA-approved disclaimer).

In 2002, FDA conducted more than 80 inspections of dietary supplement manufacturers, including a company which manufactured and marketed “Noni Fresh Juice” to treat conditions ranging from immune system disorders to arthritis, malaria, and alcohol addiction. After the inspection, the company voluntarily agreed to remove its impermissible claims.<sup>138</sup>

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FDA seized, destroyed, and sought injunctions against fraudulent dietary supplements, including “Brain Nutrient Capsules” billed as a treatment for mental retardation, epilepsy, and cerebral palsy; “Taurine Capsules” promoted to treat autism and developmental disorders; and Lane Labs’ shark cartilage product, which made unsubstantiated cancer treatment claims.<sup>139</sup>

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FDA sought criminal prosecution in the most egregious cases posing a threat to public health, including cases where individuals conspired to substitute low-price or counterfeit ingredients for the ingredients listed on the label of their dietary supplements.<sup>140</sup>

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#### Even Successful FDA Enforcement Actions Against A Dietary Supplement Manufacturer Fail to Deter Other Manufacturers

Despite FDA’s successful enforcement actions above, however, the same dubious dietary supplements targeted above continue to be sold. Internet searches reveal dozens of commercial websites still dedicated to selling Tahitian Noni Juice,<sup>141</sup> Memory Lane Brain Nutrient Lifestyle Supplements,<sup>142</sup> and BeneFin Shark Cartilage.<sup>143</sup> FDA’s actions were only effective in policing fraudulent dietary supplement claims, and failed

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<sup>141</sup>See *supra* note 36.

<sup>142</sup>See, e.g., <http://www.worldwideshoppingmall.co.uk/body-soul/memory-lane-tm.asp> (a European website selling and shipping its Memory Lane Brain Nutrient worldwide) (last visited Apr. 7, 2004).

<sup>143</sup>See, e.g., <http://www.evitamins.com/product.asp?pid=261> (selling shark cartilage pills and suggesting shark cartilage’s effectiveness against arthritis and cancer) (last visited Apr. 7, 2004).

to completely remove these dietary supplements from the market.

In short, FDA's \$500,000 annual budget for dietary supplement enforcement is simply inadequate to investigate and prosecute every violation in the \$20,000,000,000 annual dietary supplement industry. Fortunately, FDA is not alone. The FTC's more effective regulation of dietary supplement advertising is discussed in Section V.

#### D. Spam Promoting Medical Devices

Spam promoting medical devices is less frequent than spam promoting dietary supplements. However, as the "Sleep Angel" case study shows, spam promoting medical devices of dubious value still persists. Back pain in particular seems rife with possibilities for fraudulent medical devices, including "Ace Healing Machine" ("ACE's patented formula of currents and frequencies, take the body out of protection mode and into healing mode, giving prolonged pain relief and increased mobility")<sup>144</sup> and "BIO-BACK" ("The Bio-Back not only increases blood flow to all the lower extremities it increases the electrical transmission of the very important nervous system to insure proper libido.")<sup>145</sup> Apparently, a miracle medical device not only takes away your back pain, but fixes your love life as well.

Medical Device Spam Violates Statutes Regulating the Approval of Medical Devices. A new medical device cannot enter the market without FDA notification or approval. FDA classifies medical devices in three categories according to their varying degrees of risks and benefits. Class I, the least regulated category,

<sup>144</sup>E-mail from The Great Spam Archive, at <http://www.annexia.org/spam/messages/spam.025/072.html> (sent by "care@valuepost.net", Apr. 21, 2000).

<sup>145</sup>E-mail from The Spamarchive, at <http://mellin.org/spamarchive/view.jsp?id=2446>.

includes devices which do not present an unreasonable risk of illness or injury, are not intended for use to support or sustain human life, and are not substantially important in preventing the impairment of human health.<sup>146</sup> Class I devices do not require premarket approval and are subject only to general controls regarding adulteration and misbranding.<sup>147</sup> Class II devices are riskier and FDA can require performance standards to provide reasonable assurance of the device's safe and effective performance.<sup>148</sup> Finally, Class III devices include the most potentially dangerous devices and require a manufacturer to apply for FDA premarket approval.<sup>149</sup>

Class I and II devices must be registered in the FDA's Premarket Notifications (510(k)) database. Class III devices must be registered in the FDA's Premarket Approvals (PMA) database. Searches in both the FDA's 510(k) and PMA databases returned no results for "Sleep Angel", "Ace Healing Machine", or "Bio-Back."<sup>150</sup> This unsurprising result holds true for most products promoted by medical device spam. Penalties for products which circumvent the FDA's medical device approval process include mandated consumer notification of the device's risks; repair, replacement, or refund of the device; and in the most extreme cases, product recall or a total ban on marketing of the device.<sup>151</sup> Sleep Angel, Ace Healing Machine, Bio-Back – and most medical devices featured in spam – are therefore potentially subject to all of these penalties.

Sleep Angel Revisited – Effective Consumer Whistleblowing of Fraudulent Medical Devices. Consumer reporting is one of FDA's strongest tools to detect medical device fraud. Accordingly, the FDA website allows consumers to voluntarily report adverse experiences with medical devices.<sup>152</sup> These voluntary reports are

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<sup>146</sup>21 U.S.C. § 360c(a)(1)(A) (2004).

<sup>147</sup>Id.

<sup>148</sup>21 U.S.C. § 360c(a)(1)(B) (2004).

<sup>149</sup>21 U.S.C. § 360c(a)(1)(C) (2004).

<sup>150</sup>These searches were performed on Mar. 20, 2004.

<sup>151</sup>See 21 U.S.C. § 360f, 360h (2004).

<sup>152</sup>Food and Drug Administration, MedWatch Online Voluntary Reporting Form, at <https://www.accessdata.fda.gov/scripts/medwatch/> (last visited Apr. 7, 2004).



then stored in the FDA's publicly accessible Manufacturer and User Facility Device Experience (MAUDE) database which currently contains about 1,200,000 reports.<sup>153</sup> The high number of voluntary reports shows that consumers value MAUDE as a reporting tool.

FDA aggressively monitors MAUDE. A MAUDE search for "Sleep Angel" found that a patient reported potentially life threatening consequences from using the Sleep Angel device in July 2003.<sup>154</sup> The FDA subsequently interviewed the patient and the Sleep Angel product was eventually removed from the market. Robust consumer reporting tools like MAUDE are an effective way for FDA to become aware of and take action against fraudulent medical devices.

Evaluation of FDA's Fight Against Fraudulent Health Product Spam. FDA has substantial authority to regulate false claims made in spam promoting prescription drugs, fraudulent drugs, dietary supplements, and medical devices. FDA's enforcement efforts have wisely not stopped at the spam itself but have also targeted the rogue pharmacies and dubious manufacturers which supply the fraudulent products and bankroll the spam. While there have been some successes, FDA's limited enforcement resources have been inadequate to stem the rising tide of Internet health product fraud aided and abetted by spam. Fortunately, FDA is not alone. The next section discusses how the FTC has opened up a complementary front in the fight against health product spam.

## **V. The Federal Trade Commission's Actions Against Health Product Spam**

Timothy Muris, the Chairman of the Federal Trade Commission, recognizes that "Spam is one of the

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<sup>153</sup>Food and Drug Administration, Problems with Medical Devices – What Problems Have Been Reported?, at <http://www.fda.gov/cdrh/consumer/problems.html> (last visited Apr. 7, 2004).

<sup>154</sup>See MAUDE database search results for "Sleep Angel" at <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/Detail.cfm?MDRFOI> (reported July 11, 2003).

most daunting consumer protection problems the Commission has ever faced.”<sup>155</sup> Citing expert opinions from the FTC’s 2003 Spam Forum, Muris stated that “we are at a ‘tipping point,’ requiring some action to avert deep erosion of public confidence that could hinder, or even, for many, destroy, e-mail as a tool for communication and online commerce.”<sup>156</sup>

Under Muris’s leadership, the FTC has aggressively engaged the spam threat in general and health product spam in particular. This discussion first discusses the FTC’s actions against health product spam and then evaluates the FTC’s actions against the rogue pharmacies and manufacturers responsible for the fraudulent health products promoted by spam.

#### A. FTC Actions Against Health Product Spam

FTC Litigation Against Deceptive Spam. FTC has spearheaded a coalition of federal, state, and local law enforcement agencies to target deceptive spam and Internet scams. In November 2003 alone, FTC and other agencies filed 285 criminal and civil law enforcement actions against ten individuals and five corporations accused of using Internet communications for fraudulent schemes.<sup>157</sup> The targeted schemes included fake credit offers impersonating reputable companies that induced consumers to disclose sensitive financial information; fraudulent work-at-home scams; pyramid schemes for pre-packaged Internet businesses which falsely advertised potential earnings; and fake Internet auctions for electronic equipment which was never delivered.<sup>158</sup>

Specific FTC Actions Against Health Product Spam. In the last five years, the FTC has filed 105 cases challenging deceptive and misleading health claims made in advertising, most of which involved online mar-

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<sup>155</sup>FTC Chairman Timothy Muris, *The FTC and the Future Development of U.S. Consumer Protection Policy*, Remarks at the Aspen Summit (Aug. 19, 2003), available at <http://www.ftc.gov/speeches/muris/030819aspen.htm>.

<sup>156</sup>Id.

<sup>157</sup>Press Release, Federal Trade Commission, *Federal, State, and Local Law Enforcers Target Internet Scams and Deceptive Spam*, at <http://www.ftc.gov/opa/2003/11/dojsweep.htm> (Nov. 20, 2003).

<sup>158</sup>Id.

keting through spam.<sup>159</sup> The centerpiece of FTC's efforts against health product spam is Operation Cure.All. Cure.All is an ongoing effort led by the FTC and the FDA to fight deceptive and misleading Internet promotions of products and services that promise to cure serious diseases.<sup>160</sup> In Cure.All's periodic Internet surfs, the FTC and other enforcement agencies in Canada and Mexico identify websites that promote products making questionable treatment claims. The FTC then contacts the owners of these websites and threatens legal action if the claims are not corrected. Since 1999, the FTC has filed 18 Cure.All cases, stopping health product spam by stopping the websites which sponsor the health product spam.<sup>161</sup>

FTC Consumer Education Initiatives and Partnerships. Spam requires a target e-mail address. Therefore, one way to stop spam is to educate consumers on how to prevent spammers from learning their e-mail address. In the FTC's "Spam Harvest" operation, investigators seeded 250 undercover e-mail addresses across different locations on the Internet and monitored the amount of spam received for six weeks. These investigators found that spam was received by 100% of the addresses in chat rooms, 86% of the addresses in newsgroups and Web pages, 50% of the addresses on personal Web pages, and 27% of the addresses in message board postings.<sup>162</sup> These findings led to the FTC creating a consumer education website offering tips for individuals and businesses on how to avoid receiving spam.<sup>163</sup> Other consumer protection organizations disseminate similar tips and coordinate the reporting of spam violations to the FTC.<sup>164</sup> As a result, many Internet consumers have become more savvy about how improperly disclosing their e-mail address online invites health product spam.

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<sup>159</sup>See Point, Click, Self-Medicating, supra note 57 (prepared statement of Howard Beales, Director of the Bureau of Consumer Protection of the Federal Trade Commission).

<sup>160</sup>Id.

<sup>161</sup>Id.

<sup>162</sup>Press Release, Federal Trade Commission, Federal, State, and Local Law Enforcers Tackle Deceptive Spam and Internet Scams: "Spam Harvest" Results Reap Help for Consumers Trying to Avoid Spam, at <http://www.ftc.gov/opa/2002/11/netforce.htm> (Nov. 13, 2002).

<sup>163</sup>See Federal Trade Commission, SPAM EMAIL: Harvesting Your Email Address, at <http://www.ftc.gov/bcp/online/edcams/spam/> (last visited Apr. 7, 2004).

<sup>164</sup>See, e.g., the spam section of GetNetWise's Internet consumer protection website, at <http://spam.getnetwise.org/> (last visited Apr. 7, 2004).

## B. FTC Actions Against Rogue Pharmacies, Fraudulent Drugs, Dietary Supplements, and Medical Devices

The FTC has fought health product spam by suing the commercial sponsors of health product spam for false advertising and deceptive practices.

Shared FTC and FDA Jurisdiction Over Health Product Advertising. The FTC and FDA work together to regulate online health product advertising. The FTC has general authority to prevent any “false advertisement... for the purpose of inducing, or which is likely to induce, directly or indirectly the purchase of... drugs.”<sup>165</sup> Despite this general grant of authority, FTC defers to FDA’s more specific authority to regulate prescription drug advertising. As a result, FTC restricts its regulatory power to advertising for over-the-counter drugs, dietary supplements, nonrestricted medical devices, and cosmetics.<sup>166</sup> Furthermore, when FTC and FDA jurisdiction over advertising claims overlap, the FTC has stated that it will give “significant deference to the FDA’s standards” and “rely heavily on FDA’s scientific determination.”<sup>167</sup>

FTC Actions Against Rogue Pharmacies. Despite FTC’s deference to FDA for prescription drug advertising, FTC has aggressively taken action to protect consumers from unfair or deceptive practices by online pharmacies. In FTC v. Rennert, for example, the defendants’ website represented that Focus Medical Group was a full time clinic dedicated to treating sexual dysfunction and filled prescriptions on its premises.<sup>168</sup> The FTC alleged that Focus Medical Group was not a full service clinic and did not have an on-site pharmacy.<sup>169</sup>

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<sup>165</sup> 15 U.S.C. §52(a) (2004).

<sup>166</sup> Working Agreement Between FTC and FDA, 3 Trade Reg. Rep. (CCH) ¶ 9,850.01 (1971).

<sup>167</sup> Federal Trade Commission, Enforcement Policy Statement on Food Advertising § III(A)(1), § IV(B) (May 1994), available at <http://www.ftc.gov/bcp/policystmt/ad-food.htm> (last visited Apr. 7, 2004).

<sup>168</sup> FTC v. Rennert, Civ. Action No. CV-S-00-0861 JBR (D. Nev., filed July 6, 2000).

<sup>169</sup> Id.

The case settled with Focus Medical Group agreeing to not make further misrepresentations and to disclose its true medical and pharmaceutical relationships.<sup>170</sup> Additionally, Focus Medical Group agreed not to send out spam billing credit cards without customer authorization and not to sell customers' personally identifiable information without express consent.<sup>171</sup> Cases such as FTC v. Rennert show how a joint FTC and FDA regulatory regime can effectively police online pharmacies.

FTC Actions Against Fraudulent Drugs Sold Online. In Operation Cure.All, the FTC successfully filed several cases against health websites selling dubious substances which falsely purported to cure disease. These actions targeted the online promotion of cat's claw to treat cancer, AIDS, and arthritis;<sup>172</sup> the promotion of Essaic tea to treat cancer;<sup>173</sup> and the promotion of St. John's Wort to treat AIDS.<sup>174</sup> All of these cases resulted in consent decrees which required the defendants to stop the deceptive representations. These and other ongoing cases show the FTC's commitment to protecting unwitting consumers who would otherwise rely on fraudulently marketed online health products to treat serious diseases.

FTC Regulation of Dietary Supplement Advertising – Comprehensive But Eroding Standards? The FTC has taken the lead in regulating dietary supplement advertising in publishing a 32-page Dietary Supplement Advertising Guide that establishes advertising standards for the dietary supplement industry.<sup>175</sup> The Guide

<sup>170</sup>Press Release, Federal Trade Commission, Online Pharmacies Settle FTC Charges, at <http://www.ftc.gov/opa/2000/07/iog.htm> (July 12, 2000).

<sup>171</sup>See id. The FTC charged that Focus Medical Group had sent out spam to 11,000 customers informing them that their credit cards would be billed \$50 for "Y2K Remediation", which violated federal law requiring prior consumer authorization before debiting a credit card.

<sup>172</sup>See FTC v. Body Systems Tech., Inc., Dkt. No. C-3895, complaint available at <http://www.ftc.gov/os/1999/09/bodysystemcmp.htm> (Sept. 7, 1999).

<sup>173</sup>See FTC v. Michael D. Miller, d/b/a Natural Heritage Enters., Dkt. No. C-3941, complaint available at <http://www.ftc.gov/os/2000/05/michaelcmp.htm> (May 16, 2000).

<sup>174</sup>See FTC v. Panda Herbal Int'l., Inc., et al., Dkt. No. C-4018, complaint available at <http://www.ftc.gov/os/2001/08/pandacmp.htm> (July 30, 2001). See also FTC v. ForMor, Inc., et al., Dkt. No. C-4021, complaint available at <http://www.ftc.gov/os/2001/08/formorcmp.htm> (July 30, 2001).

<sup>175</sup>Federal Trade Commission, Dietary Supplements: An Advertising Guide for Industry, available at <http://www.ftc.gov/bcp/conline/pubs/buspubs/dietsupp.pdf> (Apr. 2001).

clarifies the truthfulness requirements for both express and implied claims and provides examples of prominent qualifying disclosures.<sup>176</sup> The Guide also addresses the amount, type, and quality of substantiating evidence that is required to make a dietary supplement claim.<sup>177</sup> Finally, the Guide concludes with a discussion of when using testimonials is appropriate and when the Dietary Supplement Health Education Act Disclaimer should be used.<sup>178</sup> In sum, the FTC's comprehensive advertising standards give adequate regulatory guidance for both traditional and online marketing of dietary supplements.

In a dispute between the FTC and FDA over dietary supplement advertising, however, the FTC has argued that allowing more qualified health claims for food and dietary supplements is more likely to benefit both consumers and competition, because better-informed consumers are able to make healthier choices.<sup>179</sup> In practice, the FTC's proposal would allow dietary supplements to make more qualified health claims that are supported by less than significant scientific agreement than are allowed under the current FDA regime. This dispute remains unresolved at the time of this writing. If more qualified health claims are allowed, however, this could erode the legal basis for challenges against the already relatively lightly regulated dietary supplement industry.

FTC Actions Against Fraudulent Dietary Supplements Sold Online. In 2003, the FTC challenged deceptive health care advertising for products with more than \$1 billion in sales, and most of these products were dietary supplements.<sup>180</sup> In the fight against deceptive dietary supplements sold and marketed online, FTC's

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<sup>176</sup>Id.

<sup>177</sup>Id.

<sup>178</sup>Id.

<sup>179</sup>Press Release, Federal Trade Commission, FTC to FDA: Allowing More, Truthful Health Claims for Food and Dietary Supplements Likely to Benefit Both Consumers and Competition, at <http://www.ftc.gov/opa/2004/01/foodlabeling.htm> (Jan. 29, 2004).

<sup>180</sup>Press Release, Federal Trade Commission, FTC Testifies on the Marketing of Dietary Supplements, at

Operation Cure. All lawsuits have forced manufacturers to back down from outrageous claims including the promotion of comfrey herbs in “Complete Tissue Repair Syrup” for any injury or degenerative bone, muscle, or nerve conditions;<sup>181</sup> the promotion of colloidal silver for “the promotion and treatment of all known internal and external infections”;<sup>182</sup> the promotion of tablets containing crustacean exoskeletons and Vitamin C for substantial weight loss;<sup>183</sup> and the claim that an ephedra-containing product called “Ultimate Energizer” had no side effects.<sup>184</sup> In all of these cases, FTC action resulted in the dietary supplement manufacturers agreeing to stop the deceptive representations.

FTC Actions Against Fraudulent Medical Devices Sold Online. Operation Cure. All has rounded out FTC’s assault against fraudulent health websites by targeting astonishingly audacious claims for medical devices. These FTC lawsuits targeted the “Zapper”, an electrical unit marketed to treat AIDS, Alzheimer’s, arthritis, cancer, and diabetes;<sup>185</sup> the “Portable Rife Frequency Generator” to treat cancer;<sup>186</sup> and the “Acoustic Lightwave Therapy” machine to treat arthritis, diabetes, flu, lyme disease, parasites, pneumonia, and some cancers.<sup>187</sup> All of these cases resulted in consent decrees which required the defendants to stop the deceptive representations. These and other ongoing cases show the FTC’s commitment to protecting naïve consumers who would otherwise part with their treasure for fraudulent medical devices.

<http://www.ftc.gov/opa/2003/10/dietarysupptest.htm> (Oct. 28, 2003).

<sup>181</sup>See FTC v. Western Botanicals, Inc., et al., Civ. Action No. CIV S-01-1332 DFL GGH (E.D. Cal., filed July 13, 2001), complaint available at <http://www.ftc.gov/os/2001/07/westbotcmp.pdf>.

<sup>182</sup>See FTC v. Robert C. and Lisa M. Spencer, d/b/a Aaron Co., Dkt. No. C-0419, complaint available at <http://www.ftc.gov/os/2001/08/aaroncmp.htm> (July 30, 2001).

<sup>183</sup>Id.

<sup>184</sup>Id.

<sup>185</sup>See FTC v. Western Dietary Products Co., et al., Civ. Action No. CO1-0818R (W.D. Wash., filed Dec. 26, 2001), stipulated final order and judgment available at <http://www.ftc.gov/os/2001/12/westdietorder.pdf>. See also FTC v. Dr. Clark Research Assoc., et al., d/b/a Dr. Clark Zentrum, Civ. Action No. 1:03CV0054 (N.D. Ohio, filed Jan. 8, 2002), complaint available at <http://www.ftc.gov/os/2003/01/drclarkcmp.htm>.

<sup>186</sup>See FTC v. Michael Forrest, d/b/a Jaguar Enters. of Santa Ana, a/k/a. Jaguar Enters., Dkt. No. C-4020, complaint available at <http://www.ftc.gov/os/2001/08/jaguarcmp.htm> (July 30, 2001).

<sup>187</sup>See FTC v. Biopulse Int’l, Inc., et al., Civ. Action No. C023511 (N.D. Cal., July 23, 2002), complaint available at <http://www.ftc.gov/os/2002/07/biopulse2cmp.pdf>.

Despite Some Successes, FTC's Pessimism About Stopping False Health Product Spam. The FTC has had some successes in both regulating health product spam as a medium of communication and regulating the companies which are responsible for promoting the fraudulent health products. Despite the publicity surrounding Operation Cure.All and the FTC's consumer education initiatives, however, the amount of health care spam and its associated fraud continues to rise exponentially.<sup>188</sup> In short, the FTC's and the FDA's enforcement actions are only a drop in the bucket. Indeed, even FTC Chairman Timothy Muris concedes that "[E]ventually, the spam problem will be reduced, if at all, through technological innovations."<sup>189</sup> Why does technology, not regulatory law, offer the brightest hope to stop health product spam?

## **VI. The Impact of Anti-Spam Laws and Technology on Health Product Spam**

At the intersection of technology and regulatory law are the recently enacted anti-spam laws. This section first discusses the patchwork quilt of state anti-spam laws and then evaluates their preemption by the federal "Controlling the Assault of Non-Solicited Pornography and Marketing" Act ("CAN-SPAM") of December 2003. Finally, this section discusses the lawsuits against spammers filed by a coalition of major Internet service providers under CAN-SPAM.

### **A. The Patchwork Quilt of Previous State Anti-Spam Laws.**

In July 2003, spam already accounted for 45% of all e-mail.<sup>190</sup> However, the U.S. Congress had considered

<sup>188</sup>See supra text accompanying notes 26-28.

<sup>189</sup>See FTC Chairman Timothy Muris, The FTC and the Future Development of U.S. Consumer Protection Policy, supra note 155.

<sup>190</sup>Virginia Claims Toughest Anti-Spam Law, Computer and Internet Lawyer, July 2003.



and rejected spam legislation for five straight years.<sup>191</sup> Therefore, anti-spam advocates turned to state legislatures. By July 2003, 26 states had passed anti-spam legislation.<sup>192</sup> This state legislation had some successes in protecting consumers from unwanted e-mail. The first success of state anti-spam laws occurred in 1998, when a Washington state resident named Bruce Miller settled a claim for \$200 with noni juice distributors who had sent him spam.<sup>193</sup>

Other states took a much harder line against spam. In Virginia, where half of the world's Internet traffic passes because of America Online, spam was classified as a Class 6 Felony with penalties of up to 5 years in prison, a fine, and seizure of all computer equipment and profits associated with the spam.<sup>194</sup> In December 2003, Virginia prosecutors used this law to indict two men who had allegedly sent out thousands of spam messages hawking investments, mortgage information, and software.<sup>195</sup> These men each face the prospect of 20 years in prison and \$10,000 in fines.<sup>196</sup>

Unfortunately, the state anti-spam law regimes had several glaring problems. First, Internet communications do not respect jurisdictional boundaries, and individual state resources were simply inadequate to investigate and prosecute alleged violations in other states or countries. Second, 26 inconsistent state regulatory regimes made it very costly and difficult for a legitimate e-mail marketer to comply with all of the state laws, even if the marketer knew where each potential consumer resided. Compliance with one uniform federal standard, on the other hand, would have been much more cost effective for legitimate marketers. Third, legal challenges threw doubt on whether state regulation of interstate commercial spam was incompatible with the federal

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<sup>191</sup>Id.

<sup>192</sup>Id.

<sup>193</sup>See supra text accompanying notes 121-22.

<sup>194</sup>See Virginia Claims Toughest Anti-Spam Law, supra note 190.

<sup>195</sup>Brad Wright, Virginia Indicts Two on Spam Felony Charges, CNN, at <http://www.cnn.com/2003/TECH/internet/12/12/spam.charges/index>. (Dec. 12, 2003).

<sup>196</sup>Id.

power to regulate interstate commerce. Fourth, the existing federal Computer Fraud and Abuse Act was too broadly drafted and had inadequate penalties to effectively police the spam threat.<sup>197</sup> As a result, pressure built for a comprehensive federal anti-spam law which would harmonize and preempt the patchwork quilt of state anti-spam law regimes.

#### B. The CAN-SPAM Act of December 2003

The Federal “Controlling the Assault of Non-Solicited Pornography and Marketing” Act was passed in December 2003 by a vote of 392-5 in the House of Representatives and 97-0 in the Senate. Despite this overwhelming bipartisan support, the jury is still out as to whether CAN-SPAM is effective. In a poll two months after CAN-SPAM was passed, 7 out of 10 people reported that they saw no difference in the amount of spam they received, and about 1 in 10 said spam has increased.<sup>198</sup>

Why hasn’t CAN-SPAM canned spam? The following discussion evaluates the major provisions – and major weaknesses – of CAN-SPAM.

CAN-SPAM Provisions – Preemption. The federal CAN-SPAM Act explicitly preempts state laws regulating the use of electronic mail to send commercial messages.<sup>199</sup> While this is an advantage for the reasons discussed above, in some jurisdictions CAN-SPAM actually reduced consumer protection from spam. Cal-

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<sup>197</sup>However, America Online did successfully invoke the Computer Fraud and Abuse Act in two pioneering cases against spammers. See *America Online, Inc. v. LCGM, Inc.*, 46 F.Supp.2d 444, 451 (E.D. Va. 1998); see also *America Online, Inc. v. Nat’l Health Care Discount, Inc.*, 174 F.Supp.2d 890, 899 (N.D. Iowa 2001).

<sup>198</sup>Poll: Don’t Call List Works, Spam Law Doesn’t, CNN, at <http://www.cnn.com/2004/US/02/19/ap.poll.do.not.call.ap/index.html> (Feb. 19, 2004).

<sup>199</sup>Controlling the Assault of Non-Solicited Pornography and Marketing Act, S. 877, § 8(b)(1), Dec. 2003.

ifornia's preempted anti-spam law, for example, provided for significantly more draconian penalties than CAN-SPAM.<sup>200</sup> However, CAN-SPAM explicitly preserves state fraud, contract, trespass, and tort laws that may also provide actions against spam.<sup>201</sup> Section VII addresses California computer crime and consumer protection laws to show how non-preempted state laws complement the federal regulatory regime against spam and fraudulent health products.

CAN-SPAM Criminalizes Some – But Not All – Spam. CAN-SPAM makes it a crime to access a protected computer without authorization to send multiple commercial e-mail messages.<sup>202</sup> CAN-SPAM also criminalizes spammers' common practice of sending out multiple commercial e-mail messages from falsely registered e-mail accounts, domain names, and Internet Protocol addresses.<sup>203</sup> The "multiple" requirement is met if a spammer sends out more than 100 e-mail messages in a 24-hour period, more than 1,000 e-mail messages in a 30-day period, or more than 10,000 e-mail messages in a 1-year period.<sup>204</sup> Penalties for violating these provisions include up to five years in prison, fines, and forfeiture of the profits and equipment associated with the offense.<sup>205</sup> Note, however, that these provisions do not criminalize spam which is sent out from a computer which the spammer is authorized to use, or spam that is sent from a bona fide e-mail account or domain name. This is the first of several loopholes in CAN-SPAM.

CAN-SPAM Fights Deceptive Header Information. CAN-SPAM makes it a crime to materially falsify the headers of commercial e-mail messages. Material falsification includes falsifying the identity of the sender and using a deceptive subject line that would be likely to mislead the recipient about the contents of the e-mail.<sup>206</sup> This law is crucial because 33% of spam contains a false "From" line and 22% of spam contains

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<sup>200</sup>Jacquelyn Trussell, Is the CAN-SPAM Act the Answer to the Growing Problem of Spam?, 16 Loy. Consumer L. Rev. 175, 184 (2004).

<sup>201</sup>CAN-SPAM, supra note 199, at § 8(b)(2).

<sup>202</sup>Id. at § 4(a).

<sup>203</sup>Id.

<sup>204</sup>Id.

<sup>205</sup>Id.

<sup>206</sup>Id. at § 5(a)(1)-(2).

a false subject line.<sup>207</sup> Fulfilling its title purpose to control non-solicited pornography, CAN-SPAM also requires that sexually oriented commercial e-mail be required to have labels such as “ADLT” in the subject line.<sup>208</sup> Requiring these labels would enable spam filtering software to prevent penis enlargement pill promotions from landing in a recipient’s inbox.

CAN-SPAM Requires Opt-Out Provisions. CAN-SPAM requires the sender of commercial e-mail to list a functioning e-mail address which the recipient can use to opt-out of future commercial e-mails from the sender.<sup>209</sup> It is unlawful for the sender to send further commercial e-mails to the recipient more than 10 business days after the opt out is received.<sup>210</sup> This law is also crucial because the FTC found that 62% of spam with “remove me” opt-out links did not function.<sup>211</sup> In health product spam advertising “Vigoral Herbal Love Enhancers”, for example, the opt-out e-mail address listed was: “sortofridiculous@bigfoot.com.”<sup>212</sup>

Unfortunately, most spam does not include even a false opt-out address. During February 2003, two months after CAN-SPAM went into effect, only 3% of spam included a valid link to opt out of future e-mail messages and the U.S. postal address of the sender.<sup>213</sup> In short, 97% of spam violates CAN-SPAM. Even worse, CAN-SPAM does not even prohibit all health product spam.

Even Fraudulent Health Product Spam May Comply with CAN-SPAM. Even when enforced to its fullest extent, CAN-SPAM does not prohibit all spam. Unsolicited commercial e-mails with truthful transactional information, a valid opt-out address, and a valid U.S. postal address do not violate CAN-SPAM. In short,

<sup>207</sup>Div. of Mktg. Practices, Fed. Trade Comm’n, False Claims in Spam, *supra* note 26, at 3-6.

<sup>208</sup>Id. at § 5(d).

<sup>209</sup>Id. at § 5(a)(3)-(5).

<sup>210</sup>Id.

<sup>211</sup>Federal Trade Comm’n, “Remove Me” Surf Results, at <http://www.ftc.gov/bcp/conline/edcams/spam/pubs/removeme.ppt>.

<sup>212</sup>See *supra* note 44.

<sup>213</sup>Stefanie Olsen, Study: Spammers Turning Blind Eye to the Law, CNET News.com, at <http://news.com.com/2100-1032-5156629.html?tag=nl> (Feb. 10, 2004).

CAN-SPAM by itself is inadequate to prevent consumers from receiving spam promoting fraudulent health products. Therefore, food and drug regulatory law is also needed to protect consumers from the substance of fraudulent health product claims. Thus, CAN-SPAM is best conceived of as only one of several necessary weapons in the fight against fraudulent health product spam.

C. Lawsuits under the CAN-SPAM Act.

CAN-SPAM's Rights of Action. CAN-SPAM allows the Federal Trade Commission, state attorney generals, and Internet service providers ("ISPs") to bring actions under CAN-SPAM.<sup>214</sup> Two months after CAN-SPAM went into effect, a coalition of major ISPs filed six widely publicized lawsuits against hundreds of spammers. These ISPs allege that these spammers sent hundreds of millions of messages which clogged the ISPs' computer systems and violated CAN-SPAM's requirements.<sup>215</sup>

America Online's Comprehensive Anti-Spam Complaint. America Online's complaint, for example, seeks \$100 in damages for each e-mail violating CAN-SPAM by containing false or misleading transmission information, and \$25 in damages for each e-mail containing misleading subject headings and no functioning opt-out address.<sup>216</sup> America Online's complaint complements its CAN-SPAM claims with state claims under the Virginia Computer Crimes Act for computer fraud, computer trespass, dealing in falsified bulk e-mail software, and theft of computer services.<sup>217</sup> Finally, the complaint also attacks the spammers by asserting Virginia common law claims for trespass to chattels and unjust enrichment.<sup>218</sup> A more detailed discussion of how federal, state, and common law claims provide an integrated arsenal against spam follows in Section

<sup>214</sup>CAN-SPAM, *supra* note 199, at § 7.

<sup>215</sup>Marguerite Reardon, Major ISPs United in Spam Fight, CNET News.com, at [http://news.com.com/2100-1024\\_3-5172038.html](http://news.com.com/2100-1024_3-5172038.html) (Mar. 10, 2004).

<sup>216</sup>See America Online, Inc.'s Complaint at ¶¶ 15-27, America Online, Inc. v. John Does 1-40, Civ. Action No. 04-260-A (E.D. Va. Mar. 9, 2004), available at <http://news.findlaw.com/hdocs/docs/cyberlaw/aoldoes30904cmp.pdf>

<sup>217</sup>See *id.* at ¶¶ 28-50.

<sup>218</sup>See *id.* at ¶¶ 51-65.

## VII.

The Weaknesses of Using Lawsuits to Stop Spammers. Unfortunately, lawsuits to enforce CAN-SPAM suffer from several major problems. First, as America Online's complaint against "John Does 1-40" shows, most spam defendants intentionally act to hide their identities to evade detection. It is difficult to enforce judgments against anonymous defendants. Second, an increasing number of spammers are located overseas, which raises jurisdictional costs. Third, even if the overseas spammer is found, many spammers run small shadow operations and are simply unable to pay a full judgment. Fourth, spammers are like weeds. ISPs can sue hundreds of defendants, but hundreds more will spring up in their place. If CAN-SPAM lawsuits are ineffective, then, what recourse remains against spam?

### D. The Future of the Fight Against Spam.

The Proposed "Do-Not-Email" Registry. CAN-SPAM requires the FTC to submit a report on the feasibility of establishing a Do-Not-Email registry by June 2004.<sup>219</sup> This registry would allow consumers to submit their e-mail addresses on a central list which would be prohibited from receiving spam. FTC Chairman Timothy Muris has taken a dim and public view of such a registry: "My advice to consumers would be: Don't waste the time and effort to sign up."<sup>220</sup> Why this pessimism? The FTC thinks spammers will simply ignore a Do-Not-Email registry. Also, the FTC is concerned about the prohibitive cost of managing a central list with billions of e-mail addresses and fears that spammers would hack into the registry to steal its prized database of tens of millions of consumer e-mail addresses. Despite these concerns, however, strong political pressures continue to favor a Do-Not-Email registry, and its establishment seems likely by the end of 2004.

<sup>219</sup>CAN-SPAM, *supra* note 199, at § 9.

<sup>220</sup>Mark Harrington, Bill Calls for Do-Not-Spam List, NEWSDAY, Nov. 6, 2003, at A53, available at 2003 WL 66841984.

E-Mail Authentication Systems. One way to stop spam is to prevent spammers from hiding their tracks and using false identities to induce recipients to open an e-mail. Accordingly, the major ISPs are attempting to stop spam by developing e-mail authentication systems that prevent the transmission of e-mail with false transactional information. The three main competing proposals include Yahoo!'s "DomainKeys", which verifies an encrypted digital signature; and Microsoft's "Caller ID for E-mail" and America Online's "Sender Policy Framework", which check if e-mail purportedly from an e-mail provider actually originated at that e-mail provider.<sup>221</sup> While many experts agree that adoption of a uniform authentication system will reduce spam, competition between these three proposals will prevent widespread implementation in the near future.

E-Mail Stamps. Bill Gates, the Chairman of Microsoft Corporation, has proposed that people buy e-mail "stamps" to change the economics of spam. Gates' proposal would require e-mailers to donate several seconds of their computer processing time to solving a math puzzle before sending out spam; other proposals would allow ISPs to charge a penny for each e-mail sent by bulk e-mailers.<sup>222</sup> The basic idea is to shift the cost of sending millions of messages that is currently borne by ISPs back to spammers; spammers would have to buy supercomputers to send the millions of messages they need to remain profitable! However, criticism of the costs of e-mail stamps for non-commercial users and disagreement about how such a system should be practically implemented on a global scale make implementation of e-mail stamps unlikely in the foreseeable future.

## **VII. California: How State Laws Can Help Attack Health Product Spam**

The FDA, FTC, and federal anti-spam laws provide valuable fronts in the fight against health product

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<sup>221</sup>E-mail Identity System Proposed to Combat Spam, CNN, at <http://www.cnn.com/2004/TECH/internet/02/27/email.origins.ap/index.html> (Feb. 27, 2004).

<sup>222</sup>Gates: Buy Stamps to Send E-mail, CNN, at <http://www.cnn.com/2004/TECH/internet/03/05/spam.charge.ap/> (Mar. 5, 2004).

spam. However, state laws and state law enforcement agencies have opened another equally valuable front against health product spam. This section focuses on lessons learned from California's regulatory experience because of California's reputation for tough laws against consumer fraud and computer crime. The principles of this discussion, however, apply to all state legal regimes protecting people from fraudulent (health) products and computer (spam) crimes.

#### A. State Laws Protecting Consumers from Fraudulent Health Products

States have sometimes been more aggressive than federal agencies in protecting consumers from fraudulent health products. The states' clout is shown by enforcement actions such as the California attorney general's settlement with Morinda, Inc., which prohibited the noni juice manufacturer from claiming its product could treat, cure, and prevent disease.<sup>223</sup> Successful state enforcement actions against such fraudulent health claims, however, depend on the existence of state consumer protection laws which are flexible enough to regulate health product marketing on the Internet. The following discussion focuses on California's Unfair Competition Law ("UCL") applied to fraudulent health products, because of California's aggressive UCL and its consequent status as the forum of choice of nearly half of American class action litigation.<sup>224</sup> Of course, the principles of this discussion apply generally to all state consumer protection statutes which provide claims of action against fraudulent products.

The Broad Power of California's Unfair Competition and False Advertising Laws. California's Unfair Com-

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<sup>223</sup>See *supra* text accompanying notes 115-19.

<sup>224</sup>Gail E. Lees, The Defense of Private and Governmental Unfair Competition Law Claims, Practising Law Institute Order Number H0-00M8, Aug. 2003, at 297.



petition Law prohibits “any unlawful, unfair or fraudulent business act or practice and unfair, deceptive, untrue or misleading advertising.”<sup>225</sup> California’s False Advertising Act (“FAA”) complements the UCL and prohibits statements “concerning... real or personal property or services... concerning any circumstance or matter of fact connected with the proposed performance or disposition thereof, which is untrue or misleading.”<sup>226</sup> The FAA explicitly includes statements made over the Internet.<sup>227</sup> Under both the UCL and the FAA, it is not necessary to establish actual deception, reasonable reliance, or damage. It is only necessary to show that members of the public are likely to be deceived by the false business practice or advertising.<sup>228</sup> Thus, the California UCL and FAA provide broad and sweeping legal authority for consumers to fight back against fraudulent health products and fraudulent health product spam. To win a claim, it is not necessary to sue on behalf of an embarrassed consumer who will publicly confess to being physically injured by Pinnacle Penis Enlargement Pills. It is only necessary to show that some insecure man might be duped into buying the fraudulent health product.

California’s UCL and FAA Applied To Fraudulent Health Products. California courts have affirmed the power of the UCL and FAA to curb false advertising for dietary supplements. In Consumer Justice Center v. Olympian Labs, Consumer Justice Center sued to remove two dietary supplements from the market because the supplements were neither safe nor effective for their marketed purposes of weight loss and relief from Herpes simplex viruses.<sup>229</sup> The California Court of Appeal found that Consumer Justice’s UCL and FAA claims were not preempted by either the federal FDCA or the Federal Trade Commission Act.<sup>230</sup> In short, California’s UCL provides an aggressive vehicle to attack fraudulent health products and claims even when federal statutes

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<sup>225</sup>Cal. Bus. & Prof. Code § 17200 (2004).

<sup>226</sup>Cal. Bus. & Prof. Code § 17500 (2004).

<sup>227</sup>Id.

<sup>228</sup>See Comm. on Children’s Television v. General Foods, 35 Cal. 3d 197, 211 (1983).

<sup>229</sup>See Consumer Justice Center v. Olympian Labs, 99 Cal. App. 4th 1056, 1058 (2002).

<sup>230</sup>See id. at 1062 and 1066.

are silent and federal agencies have failed to take enforcement actions.

State Consumer Protection Laws Applied To Spam Promoting Fraudulent Products. Several states have passed statutes which protect consumers from fraudulent spam in terms which are not preempted by CAN-SPAM. In California, fraudulent spammers are liable for the crime of knowingly accessing without authorization a computer system in order to devise or execute a fraudulent or deceptive scheme.<sup>231</sup> This statute criminalizes the common scenario in which a spammer hijacks an ISP's computer system in order to send e-mails peddling fraudulent health products to the ISP's customers. In Washington, Microsoft has invoked the state Consumer Protection Act's prohibition of unfair or deceptive acts in trade or commerce to seek treble damages against spam promoting fraudulent products.<sup>232</sup>

State unfair competition and false advertising laws complement federal consumer protection laws and allow states and private parties to effectively prevent fraudulent health products and fraudulent e-mail advertisements from reaching consumers. State law contributions to the fight against fraudulent health product spam, however, are not limited to consumer protection statutes, but also include state computer crime laws.

#### B. State Computer Crime Laws Applied Against Spam

While CAN-SPAM preempts state laws regarding the use of electronic mail to send commercial messages, CAN-SPAM explicitly preserves state fraud, contract, trespass, and tort laws that may also provide actions against spam.<sup>233</sup> CAN-SPAM also does not preempt state computer crime statutes that provide important

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<sup>231</sup>Cal. Penal Code § 502(c)(1) (2004).

<sup>232</sup>See Microsoft's Complaint at ¶ 52, *Microsoft Corp. v. John Does 1-50 d/b/a Super Viagra Group*, No. CV04-0516 (W.D. Wash. Mar. 9, 2004), available at <http://news.findlaw.com/hdocs/docs/cyberlaw/mssprviag30904cmp.pdf>.

<sup>233</sup>CAN-SPAM, *supra* note 199, at § 8(b)(2).

rights of action which can be used against fraudulent spam. Accordingly, America Online has used the Virginia Computer Crimes Act and Microsoft has used the Washington Commercial Electronic Mail Act to file lawsuits against spammers.<sup>234</sup> In California, Yahoo! has used California's Computer Crime statute, Cal. Penal Code § 502, to file suit against spammers. Yahoo!'s § 502 lawsuit provides a model for litigation invoking comprehensive state causes of action against spammers. In its complaint, Yahoo! alleges that defendants knowingly accessed without authorization Yahoo!'s computer systems to wrongfully control or obtain money, property, or data in violation of § 502(c)(1); that defendants' transmission of unsolicited bulk commercial e-mail used Yahoo!'s computer services without permission in violation of § 502(c)(3); and that defendants' activities disrupted Yahoo!'s computer services for authorized users in violation of § 502(c)(5).<sup>235</sup> Penalties under § 502 vary according to the amount of damage caused, with a maximum penalty of three years in prison, a \$10,000 fine, compensatory damages to the owner of the damaged computer system, and forfeiture of all equipment used to commit the computer crime.<sup>236</sup>

In sum, the federal CAN-SPAM Act and state computer crime statutes complement each other to provide a comprehensive array of claims against spammers. While litigation against anonymous overseas spammers remains difficult, the combined federal and state lawsuits filed by ISPs against hundreds of John Doe spammers is surely a step in the right direction.

### **VIII. Private Remedies Against Health Product Spam**

The fight against health product spam is being waged by the FDA, FTC, state attorney generals, and

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<sup>234</sup>See Microsoft's Complaint, *id.*, at ¶¶ 48-51; see also America Online, Inc.'s Complaint, *supra* note 215.

<sup>235</sup>See Yahoo!'s Complaint at ¶¶ 72-76, *Yahoo! Inc. v. Eric Head et al.*, No. C04-00965 (N.D. Cal. Mar. 8, 2004), available at <http://news.findlaw.com/hdocs/docs/cyberlaw/yahoohead30904cmp.pdf>.

<sup>236</sup>Cal. Penal Code § 502(d)-(e), (g) (2004).

the major ISPs. Yet health product spam affects virtually all computer users. What private rights of action are available for individual consumers to fight back? The following discussion evaluates the effectiveness of private lawsuits against the manufacturers of fraudulent health products, private lawsuits against spammers, and technological remedies.

A. Private Lawsuits Against Fraudulent Health Product Manufacturers

Remedies for Injured Consumers. Injured consumers of fraudulent health products have many claims against manufacturers under both federal and state law. Consumers can sue under the federal Lanham Act's unfair competition claims, which courts have recognized are "substantially congruent" to claims available under state laws such as California's UCL.<sup>237</sup> If a consumer is physically injured by using the fraudulent health product, the consumer may be able to sue the manufacturer under theories of strict liability, negligence in not taking reasonable care to avoid exposing consumers to unreasonable risk of harm resulting from use of the product, breach of the duty to warn, and breach of warranty.

Remedies for Uninjured Consumers. Most fraudulent health products, however, do not injure the consumers using the product. (Pinnacle Penis Enlargement Pills aren't poisonous – they simply fail to fulfill their promise of a "Massive Penis Overnight.") While the federal FDCA does not create a private right of action for misbranding, an uninjured consumer may still be able to sue under state law for misrepresentations in advertising and labeling of the product. These consumers may also be able to sue online pharmacies which act as sponsors of the fraudulent spam advertising and distributors of the fraudulent health products. The worst rogue pharmacies, however, constantly migrate between temporary websites to evade enforcement and are located in foreign jurisdictions where it is difficult to enforce judgments.

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<sup>237</sup>See Gail E. Lees, The Defense of Private and Governmental Unfair Competition Law Claims, *supra* note 224 at 309.

Activism by Public Interest Organizations. While it is practically unlikely that the consumer of a fly-by-night dietary supplement such as “A Pill to Increase Your Ejaculation by 581%” would have the personal courage or financial incentive to hale the manufacturer into open court, public interest groups have stepped into the fray to make fraudulent health product manufacturers more accountable.<sup>238</sup> Lawsuits by organizations such as Consumer Justice Center<sup>239</sup> and public education campaigns by organizations such as Center for Science in the Public Interest and the Health Research Group are having an effect on preventing consumers from being duped by fraudulent health products promoted by spam.<sup>240</sup> Despite the efforts of these public interest groups, however, fraudulent health products marketed over the Internet continue to proliferate.

#### B. Private Lawsuits Against Spammers

Individual lawsuits against spammers are unlikely and would probably be ineffective. First, it is unlikely that an individual would have the financial incentive to justify the costs of suit. Second, even if the individual is willing to file suit, spammers hide their identities using forged headers and other technological means, which makes them difficult to find and sue. Third, courts have taken a dim view of plaintiffs’ common law claims against spam when, as with most spam, there is only incidental damage or network disruption.<sup>241</sup> Fourth, there are simply too many spammers. Suing one spammer will not make a practical difference in the amount of spam received. Fifth, as discussed below, the new CAN-SPAM Act does not provide a private right of action.

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<sup>238</sup>See supra text accompanying note 40.

<sup>239</sup>See Consumer Justice Center v. Trimedica International, Inc. et al., 107 Cal. App. 4th 595 (2003) (action against Grobust, an herbal supplement pill marketed to enlarge women’s breasts, for consumer fraud and false advertising); see also Consumer Justice Center v. Olympian Labs, supra note 229.

<sup>240</sup>Both organizations maintain websites offering frequently updated information for consumers of food and drugs. See Center for Science in the Public Interest’s website at <http://www.cspinet.org/> and Health Research Group’s website at <http://www.citizen.org/hrg/> (last visited Apr. 7, 2004).

<sup>241</sup>See, e.g., Intel Corp. v. Hamidi, 71 P.3d 296 (Cal. 2003) (California Supreme Court denied Intel’s trespass to chattels claim because Intel did not prove the defendant’s mass e-mails damaged or impaired Intel’s computer systems).

CAN-SPAM's Lack of A Private Right of Action. CAN-SPAM allows the Federal Trade Commission, state attorney generals, and ISPs to bring actions under CAN-SPAM.<sup>242</sup> However, CAN-SPAM does not provide a right of action for individuals or businesses who are damaged by spam. Ari Schwartz, associate director of the influential Center for Democracy and Technology, asserts that the failure to provide a private right of action will weaken the fight against spam: “The Center for Democracy and Technology believes that a private right of action would have helped stop spam, but the main parts of this bill – giving FTC, attorneys general, and ISPs better opportunities to sue – should help the situation.”<sup>243</sup>

Despite the superficial popular appeal of a private right of action, however, allowing ISPs to sue under CAN-SPAM overcomes all of the weaknesses discussed above. ISPs have the most financial incentive and technological savvy to file suit, because ISPs control the Internet communications infrastructure. Courts are more likely to favor claims by ISPs over other private parties, because ISPs can prove that spam causes substantial damage and disruption to their computer systems. And the major ISPs – America Online, Microsoft, and Yahoo – have the resources to sue hundreds of spammers, making deterrence more effective. By providing a right of action to ISPs but denying a general private right of action, CAN-SPAM wisely allocates scarce litigation resources to those for whom spam matters most. Indeed, for ISPs being crippled by the mounting costs of filtering billions of spam messages, the success of CAN-SPAM litigation can literally mean life or death.

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<sup>242</sup>CAN-SPAM, *supra* note 199, at § 7.

<sup>243</sup>Rebecca Porter, *Smothered by Spam*, 40 *Trial* 50, 56 (2004).

### C. Technological Remedies

The most effective solution against spam may be technological, not legal. FTC Chairman Timothy Muris concedes that “[E]ventually, the spam problem will be reduced, if at all, through technological innovations.”<sup>244</sup> John Higgins, the head of the information technology industry body in the UK, concurs: “I am afraid as a general rule, regulation is the last thing you should resort to. The most likely solution is going to be technological spam filters that go back to where [spam] originates and try to cut it out at that point.”<sup>245</sup> However, even Brightmail’s spam filters, the most effective filters in the industry, only block 95% of spam – billions of spam still slip through the cracks.<sup>246</sup> To make matters worse, Brightmail’s filters are too expensive for all but the largest companies. This forces smaller companies to dedicate employees to filtering out spam or – as most individuals do – simply endure larger and larger amounts of spam.<sup>247</sup>

While spam filters are the most widespread anti-spam technology, developing technologies such as e-mail authentication systems and e-mail stamps (discussed supra Section VI.C) may also empower private parties to stop spam. In the end, spam generally – and health product spam in particular – will only be stopped through combining the powers of health and technology regulatory law and through coordinating enforcement at the federal, state, and private levels.

## IX. Proposals for a More Effective Fight Against Health Product Spam

The multifaceted fight against fraudulent health product spam has had some successes. It is clear, however, that this fight can and must be prosecuted more effectively to protect consumers. The following discussion suggests specific reforms for the legislative, enforcement, and technological fronts of the fight against health

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<sup>244</sup>See FTC Chairman Timothy Muris, The FTC and the Future Development of U.S. Consumer Protection Policy, supra note 155.

<sup>245</sup>Nick Easen, Corporations Facing Spam Headache, CNN, at <http://www.cnn.com/2004/WORLD/europe/01/14/globaloffice.spam/index.html> (Jan. 14, 2004).

<sup>246</sup>See Spam Levels Will Peak at 80% of All Internet E-Mail, supra note 8.

<sup>247</sup>Bruce E. H. Johnson, Is There a Constitutional Right to Bombard the Public With Penis Enlargement Proposals?, Communications Lawyer, Summer 2003, at 4.

product spam.

A. Legislative Reforms for Internet Health Product Marketing

The Need to Balance Freedom and Accountability For Commercial Speech. Health product marketers enjoy the freedom of commercial speech and consumers have the right to receive information, even information of uncertain scientific value, about drugs, dietary supplements, and medical devices. On the other hand, FDA and other regulatory agencies have a mandate to protect consumers from fraudulent products and make health product manufacturers accountable for their marketing claims. These free speech and regulatory interests often collide.<sup>248</sup> Considering that 69% of claims in health product spam are false, however, stronger legislation is necessary in the e-mail communication medium to make health product marketers more accountable for their claims.<sup>249</sup>

Proposed Registration and Bail Requirements for Health Product Marketers. Considering the rampant fraud in health product spam, FDA could require health product e-mail marketers to register personally verifiable information with the FDA and post bail before e-mails can be sent to consumers. To avoid the specter of prior restraints, FDA will not review the content of health product e-mails before they are sent to consumers. If a threshold number of consumers complains to the FDA about fraudulent claims in that marketer's e-mail, however, the FDA will review the e-mail, deduct appropriate penalties from the marketer's bail, and contact the marketer to ensure future compliance with FDA standards. Continued noncompliance with FDA's standards would be punishable as a criminal offense.

<sup>248</sup>For an excellent discussion of this issue, see generally Evans, George W. and Friede, Arnold I., The Food and Drug Administration's Regulation of Prescription Drug Manufacturer Speech: A First Amendment Analysis, 58 Food & Drug L. J. 365 (2003).

<sup>249</sup>See Div. of Mktg. Practices, Fed. Trade Comm'n, supra note 26, at 10.



Proposed Joint Health Product Manufacturer and Marketer Liability. A simpler proposal would make health product manufacturers and online pharmacies strictly liable for the practices of e-mail marketers they hire. This would prevent the financial supporters of spam from shifting liability and responsibility for making fraudulent health product claims on anonymous third-party spammers. Furthermore, this proposal would encourage the lowest cost avoider – the manufacturers and pharmacies who know their health products best – to pre-approve claims in their e-mail marketing before they reach millions of consumer inboxes.

B. Legislative Reforms to Strengthen the Anti-Spam Regime

The problem of health product spam cannot be controlled by health product marketing reforms alone. The following proposals aggressively expand CAN-SPAM to address the mounting spam threat.

Proposed Opt-In Only Provisions To Ban All Spam. As discussed above, CAN-SPAM does not ban all unsolicited commercial e-mail. In the simplest and most draconian solution, the U.S. could follow the European Union’s example and allow commercial e-mails to be sent only to consumers who initiate contact with the marketer and requested to be put on a mailing list. This proposal would make all unsolicited commercial e-mail illegal. Empirically, however, it is difficult to determine the actual effectiveness of the European Union opt-in regime compared to the weaker CAN-SPAM regulations in the United States.<sup>250</sup> Also, a total ban on all unsolicited commercial e-mail might be too restrictive for the Central Hudson commercial speech regulation test.<sup>251</sup>

Proposed Safeguards for Consumer Privacy. Especially in the sensitive area of health product preferences,

<sup>250</sup>See Bruce E. H. Johnson, Is There a Constitutional Right to Bombard the Public With Penis Enlargement Proposals?, supra note 247, at 6.

<sup>251</sup>See id. at 7-8.

new anti-spam legislation should better regulate e-mail marketers' obligations to respect consumers' privacy. Specifically, e-mail marketers should not be able to sell lists to unrelated third parties unless the owner of the list has provided notice and the ability to be removed from such transfer to each e-mail address on the list. This reform would prevent spammers' common practice of selling lists of consumer e-mail addresses which, of course, leads to more spam. Furthermore, commercial e-mails should contain the sender's privacy policy, either within the body of the e-mail or via a link to the sender's website. This reform gives a consumer fair notice about who else will learn that he responded to an e-mail solicitation to buy discount Viagra. These proposals are simply common sense, and have even been endorsed by the American Association of Advertising Agencies, the Association of National Advertisers, and the Direct Marketing Association.<sup>252</sup>

Proposed Aggravated Penalty for Fraudulent Unsolicited Commercial E-Mail. CAN-SPAM should include an aggravated penalty for unsolicited commercial e-mail which contains fraudulent claims. The case for including an aggravated penalty is especially strong for fraudulent health product spam, because a consumer purchasing a fraudulent health product may rely solely on the fraudulent medication, forego treatment with an approved prescription drug, and die from an unchecked serious disease.

Proposed Bounties for Spam Hunters. CAN-SPAM calls for the FTC to submit a report by September 2004 about the feasibility of bounties for spam hunters. This proposal would reward people who identify a spammer and supply information leading to collection of a CAN-SPAM civil penalty with not less than 20% of the penalty.<sup>253</sup> This proposal should become law because it will restore incentives and solve the collective action problems discussed supra Section VIII.B.

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<sup>252</sup>Press Release, Direct Marketing Association, Largest U.S. Advertising and Marketing Trade Groups Release Guidelines That Establish Standards for Legitimate E-mail Marketing Practices, at <http://www.ana.net/govt/what/10.14.03.cfm> (Oct. 14, 2003).

<sup>253</sup>CAN-SPAM, supra note 199, at § 11(1).

Proposed Labeling Requirements for Commercial E-Mails. CAN-SPAM also calls for the FTC to submit a report by June 2005 about requiring commercial e-mail to be identifiable by its subject line.<sup>254</sup> This builds on CAN-SPAM's current requirement that the subject lines of sexually oriented commercial e-mail contain a prefix such as "ADLT".<sup>255</sup> Requiring mandatory labeling like "ADV" for all commercial spam, or "HLTH" for health product spam, would allow spam filters to easily discard illegitimate e-mail. Although foreign spammers are unlikely to comply with these requirements, this proposal would effectively regulate domestic spammers and should also become law.

Preemptive Action Against Mobile Spam. If receiving penis enlargement spam in your inbox is jarring, receiving penis enlargement spam at random intervals on your mobile phone is even more invasive. To its credit, CAN-SPAM requires the Federal Communications Commission and FTC to promulgate rules against mobile spam by September 2004.<sup>256</sup> Strong preemptive rules and penalties may be able to nip U.S. mobile spam in the bud. The alternative is passively waiting for the millions of mobile spam messages which European and Japanese consumers already receive.<sup>257</sup>

C. Making Enforcement Against Fraudulent Internet Health Products More Effective

Proposed Public Reporting Database to Increase Consumer and Regulatory Agency Knowledge of Fraudulent Internet Health

Effective consumer protection and regulatory enforcement requires rapid awareness of what fraudulent health products are being marketed on the Internet. Unfortunately, the current system largely fails to deliver fraud-

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<sup>254</sup>Id. at § 11(2).

<sup>255</sup>Id. at § 5(d).

<sup>256</sup>Id. at § 14.

<sup>257</sup>See text accompanying notes 9-12.

ulent product information to the public in a timely and efficient manner. While FDA databases such as MAUDE allow centralized consumer reporting for medical device problems,<sup>258</sup> most consumer reporting databases are not easy to find and are not user-friendly. The public would be better served if the FDA and FTC could jointly maintain a regularly updated database containing all of the fraudulent health products, manufacturers, and rogue pharmacies that exploit Internet marketing. If manpower is scarce, the integrity of consumer submissions to this database could be reviewed by the many existing public interest health organizations. This proposal would more quickly identify and disseminate knowledge of fraudulent health products marketed on the Internet, educating consumers and enabling rapid enforcement action.

Increasing the Frequency of Cure.All Internet Surfs. There are simply too many spammers and too few prosecutions for effective deterrence in scaring fraudulent health product marketers into compliance. In other words, the 18 successful Operation Cure.All lawsuits discussed in Section V are only a drop in the bucket. Part of the problem is that regulatory agencies do not know who the fraudulent health product marketers are. From 1997 to 2002, for example, there were only 3 Operation Cure.All “Internet surfs” to identify fraudulent health product websites.<sup>259</sup> Adopting reforms such as the public database proposal above and holding more frequent Internet surfs would allow regulatory agencies to identify more fraudulent health product marketers and file more lawsuits.

Increasing the Frequency of Internet Health Business Inspections. Regular inspections of the physical premises of online pharmacies such as Focus Medical Group<sup>260</sup> and dietary supplement manufacturers such as Fresh Vitamins<sup>261</sup> have prevented fraudulent and deceptive practices. Claims about Internet health product busi-

<sup>258</sup>See text accompanying notes 86-87 and 153-154.

<sup>259</sup>See Point, Click, Self-Medicare, *supra* note 57 (prepared statement of Howard Beales, Director of the Bureau of Consumer Protection of the Federal Trade Commission).

<sup>260</sup>See text accompanying notes 168-71.

<sup>261</sup>See text accompanying note 112.

nesses in particular are easy to misrepresent because the consumer only sees the front of a website, not the front of a building. The FDA, FTC, and state boards of pharmacy should coordinate their efforts to preemptively ensure Internet health product businesses are truthfully representing themselves instead of waiting for injured consumers to complain.

#### Three Proposals to Increase the Quantity and Quality of Fraudulent Internet Health Product Prosecutions.

Even after regulatory agencies identify a fraudulent health product, warning letters are ignored by 80% of Internet health businesses.<sup>262</sup> Full prosecutions are needed for full deterrence. The most straightforward method to increase the quantity of prosecutions is to increase government funding for Operation Cure. All lawsuits. A second method is to eliminate duplication of scarce enforcement resources by promoting more formal interagency working groups between the FDA, FTC, state, and local enforcement agencies rather than the current informal framework of ad hoc meetings. A third method is to reward private attorney generals by providing them 20% of the civil penalty which a fraudulent Internet health product marketer would normally pay to the government. This proposal would swell the army of available enforcement agents and justly reward organizations like Consumer Justice Center who protect naïve consumers from fraudulent health products.<sup>263</sup>

#### D. Maximizing Potential Anti-Spam Technologies

Proposed Identity Verification for Free E-mail Accounts. Spammers who make illegal health product claims

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<sup>262</sup>See text accompanying note 78.

<sup>263</sup>See supra notes 229 and 239.

often sent out e-mail from free e-mail accounts. When registering for these accounts, spammers use false personal information in order to hide their tracks from later investigators. Requiring identity verification for free e-mail accounts would close this door to spammers. Identity verification could be easily implemented through age verification systems already used by many adult websites or credit card verification systems similar to those used by airport self-service check-in kiosks. Identity verification would also reduce the incidence of other computer crimes such as credit card phishing, where an anonymous spammer defrauds the recipient into revealing sensitive financial information.

Proposed Blacklist Registry. Instead of a “Do-Not-Spam” registry, the major ISPs could maintain a centralized blacklist registry of known spammers’ e-mail addresses. E-mail users at the major ISPs already have the option to blacklist e-mail addresses, and a dynamically updated blacklist which aggregates contributions from all users could potentially enable all major ISPs to shut down all spam emanating from a particular e-mail address in a matter of minutes.

While critics point out that it is easy for a spammer to register a new e-mail address once the old address has been shut down, this proposal would still be able to cut down on spam faster than existing systems. Critics might also point to the possibility that legitimate addresses could be blacklisted, unjustifiably suppressing speech. However, requiring a relatively high threshold number of complaints and a scan of the submitted e-mail’s text for commercial content before an e-mail address is blacklisted should minimize false reports.

Government Partnerships with ISPs to Support Anti-Spam Technology. The major ISPs, not governmental agencies, are making the key innovations in anti-spam technology that will have the most practical effect on your inbox. Accordingly, the FTC and FCC should hold periodic meetings with the major ISPs to keep apprised of the latest developments in anti-spam technology. The FTC could even commission anti-spam technology by establishing prizes for the best solutions to problems such as ensuring security for a Do-Not-Email registry or how best to dynamically update a Blacklist registry.

While government should leave technical innovation to the industry which knows e-mail best, once an anti-spam standard is widely adopted by the major ISPs – whether Yahoo!’s “DomainKeys” or Microsoft’s “Caller ID for E-mail” – the government should strongly encourage all ISPs, and foreign countries, to quickly adopt that standard. After all, the effectiveness of anti-spam technology generally increases directly with the number of ISPs adopting that technology. The U.S. government should not sit on the sidelines waiting for private actors and foreign governments to act.

Government Partnerships With Legitimate Marketers to Fight Spam. Legitimate advertisers, worried that spammers are alienating consumers from all commercial e-mail advertising, are natural partners to support federal anti-spam enforcement. In Operation Slam Spam, the Direct Marketing Association is giving “formal assistance and major resources” for the Federal Bureau of Investigation to identify and prosecute spammers.<sup>264</sup> Industry assistance is invaluable for enforcement agencies with limited financial resources, and the FDA and FTC should actively encourage similar partnerships with legitimate Internet health product businesses whose credibility is also threatened by fraudulent health product spam.

Government Partnerships With Foreign Governments. Spam increasingly comes not from the United States, but from foreign countries. Thus, cooperation with foreign governments is essential in order to identify and prosecute foreign spammers. Cooperation can take the form of foreign governments encouraging foreign ISPs to honor U.S. subpoenas that can help identify spammers, the passage of reciprocal spam prosecution laws, and extradition of the worst offenders to the United States. To their credit, some foreign governments have already aggressively engaged this problem. Nigeria, for example, has appointed a presidential panel to stop economic crimes committed via the Internet in response to ubiquitous (and profitable) “Nigerian letter

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<sup>264</sup>See Direct Marketing Association, DMA Statement re: Operation Slam Spam, supra note 21.

fraud” scams.<sup>265</sup> Similar high level cooperation from other foreign governments will be necessary to stop the rising flood of foreign spam.

## **X. Concluding Remarks**

Fraudulent health product spam is a complex and daunting problem. Legally, stopping fraudulent health product spam requires the creative intersection of federal food and drug laws, federal anti-spam laws, state unfair competition laws, and state computer crime laws. Practically, stopping fraudulent health product spam requires careful coordination between the FDA, FTC, state attorney generals, and the major ISPs. In the future, stopping fraudulent health product spam will require the development and deployment of innovative anti-spam technologies.

Technology changes, but the need to protect consumers from fraudulent health products remains constant. Fraudulent health product spam forces existing legal and regulatory systems to adapt to meet the demands of a rapidly changing technological medium. Speedy and successful adaptation to new demands depends on a candid evaluation of what works, what does not work, and what may work in the future. This paper’s objective is to make this candid evaluation for the purpose of reducing fraudulent health product spam.

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<sup>265</sup>See Anita Ramasastry, Why the New Federal ‘CAN-SPAM’ Law Probably Won’t Work, CNN, at <http://www.cnn.com/2003/LAW/12/05/findlaw.analysis.ramasastry.spam/index.html> (Dec. 5, 2003). In a “Nigerian letter fraud” scam, foreign spammers claim to represent the Nigerian government and lull the recipient into disclosing their bank account information through a seemingly legitimate business proposal.