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March 27, 2006

VIA ELECTRONIC FILING

Marlene H. Dortch, Secretary
Federal Communications Commission
445 12th Street, S.W.
Washington, D.C. 20554

Re: Notice of *Ex Parte* Communications
CG Docket Nos. 02-278 & 05-338

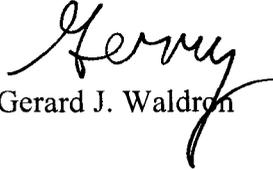
Dear Ms. Dortch:

Last Friday, Jade West, Senior Vice President of Government Relations of the National Association of Wholesaler-Distributors and Director of the Fax Ban Coalition, and Gerard J. Waldron and Robert M. Sherman of Covington & Burling met with Commission staff to discuss the Commission's rulemaking to implement the provisions of the Junk Fax Prevention Act of 2005 ("JFPA").

Ms. West and Messrs. Sherman and Waldron met with Jessica Rosenworcel of Commissioner Copps' staff; Messrs. Sherman and Waldron met with Scott Bergmann of Commissioner Adelstein's staff; and Mr. Waldron met via telephone with Jay Keithley of the Consumer and Governmental Affairs Bureau. During these meetings, we emphasized that the Commission does not have authority at this juncture to impose time limitations on established business relationships. In addition, the Coalition explained that, in light of the wide variety of industries and business relationships regulated by the JFPA, the Commission must adopt flexible rules that do not impose unrealistic regulatory and litigation burdens on senders of legitimate business faxes.

The attached handouts were used during these meetings.

Sincerely,


Gerard J. Waldron

cc: Jessica Rosenworcel
Scott Bergmann
Jay Keithley

THE FAX BAN COALITION**Junk Fax Prevention Act of 2005
CG Docket No. 05-338**

The established business relationship preserves the ability to conduct legitimate business.

- The Commission is not yet empowered to impose a time limit on EBRs. Before doing so, it must meet the four requirements in section 2(f) of the JFPA.
- The EBR definition proposed in the NPRM should be adopted.
- Congress intended not to require a writing to demonstrate invitation or permission to send a fax.

Compliance requirements must be flexible and workable.

- The organizations, industries, and relationships subject to the TCPA are diverse and varied. An attempt to impose specific permission or recordkeeping requirements will necessarily be both under- and over-inclusive.
- Senders should be permitted to use faxes listed in directory entries if they have a reasonable basis for believing the fax numbers were provided voluntarily. Specific due diligence requirements would eliminate efficiencies associated with directory use, and would therefore stop senders from using them.
- Because senders will keep records that are necessary and efficient to respond to lawsuits under the TCPA and JFPA, it is unnecessary for the FCC to impose specific recordkeeping requirements regarding the existence of EBRs, voluntary provision of fax numbers, and invitation or permission to fax.

The rules implementing the JFPA's opt-out scheme must be realistic.

- The Commission should adopt the definition of “clear and conspicuous” that it used in its MSCM rules: *The notice “must be clearly legible, use sufficiently large type . . . and be placed so as to be readily apparent” to a recipient.*
- The Order should provide a “safe harbor” list of opt-out notice elements, whereby senders will know that any opt-out notice including the listed elements will be sufficient. (Senders should have discretion to add or remove content from the notice based on relevant circumstances.)
- Senders should have discretion to identify the cost-free mechanisms that are most efficient for their recipients and their businesses.
- For faxes sent by a fax transmitter, opt-out requests should apply only to the sender on whose behalf the fax was sent, not to all senders that use the transmitter.
- Thirty-one days is an appropriate “shortest reasonable time” for the honoring of opt-out requests.

THE FAX BAN COALITION**Junk Fax Prevention Act of 2005
CG Docket No. 05-338****NO TIME LIMIT ON EBR**

The Commission has no authority at this juncture to impose a time limitation on EBRs.

- In section 2(f), the JFPA gives the FCC authority to impose time limitations on EBRs but requires that, “*before establishing any such limits, the Commission shall,*” in part, “*determine whether the [new EBR] has resulted in a significant number of complaints....*”
- Because the Commission has no experience with its new rules, it is impossible for the FCC to evaluate its experience as required by the statute. Accordingly, the Commission cannot impose a time limitation in this rulemaking.

Adopting a time limitation at this juncture would be contrary to Congressional intent.

- While the House of Representatives was considering the JFPA, Congressman Markey explained the purpose behind the time limitation provision:

The legislation will permit the Commission to put in place a [duration limit on] the established business relationship, *after the FCC implements the new opt-out policy and it gets a track record on what is happening in the marketplace.* In particular, the Commission will examine consumer complaints to the agency *during this period* with an analysis as to whether junk faxes [cause] a significant number of complaints.

150 Cong. Rec. H6089-02 (emphasis supplied).

The JFPA's new framework introduces new dynamics with which the FCC has no experience.

- The JFPA paired an EBR with a mandatory opt-out requirement in order to increase recipients' ability to choose, and to reduce burdens on senders and recipients alike. Specifically, the EBR facilitates faxes between businesses and customers, but the new opt-out requirement gives recipients the ability to prevent faxes from specific senders.
- Although the FTC has limits on EBR in the telemarketing context, those rules are quite different in that the JFPA's EBR exception applies to both business-to-business and business-to-consumer communications.
- In contrast to other areas in which the FCC commonly regulates, the JFPA involves a wide range of industries and business relationships. Before regulating in this area, Congress intended the Commission to take the time to fully understand the complexities associated with regulating a diverse group of industries.

“(v) the telephone and facsimile machine numbers and the cost-free mechanism set forth pursuant to clause (iv) permit an individual or business to make such a request at any time on any day of the week; and

“(vi) the notice complies with the requirements of subsection (d);”.

(d) **REQUEST TO OPT-OUT OF FUTURE UNSOLICITED ADVERTISEMENTS.**—Section 227(b)(2) of the Communications Act of 1934 (47 U.S.C. 227(b)(2)), as amended by subsection (c), is further amended by adding at the end the following:

“(E) shall provide, by rule, that a request not to send future unsolicited advertisements to a telephone facsimile machine complies with the requirements under this subparagraph only if—

“(i) the request identifies the telephone number or numbers of the telephone facsimile machine or machines to which the request relates;

“(ii) the request is made to the telephone or facsimile number of the sender of such an unsolicited advertisement provided pursuant to subparagraph (D)(iv) or by any other method of communication as determined by the Commission; and

“(iii) the person making the request has not, subsequent to such request, provided express invitation or permission to the sender, in writing or otherwise, to send such advertisements to such person at such telephone facsimile machine;”.

(e) **AUTHORITY TO ESTABLISH NONPROFIT EXCEPTION.**—Section 227(b)(2) of the Communications Act of 1934 (47 U.S.C. 227(b)(2)), as amended by subsections (c) and (d), is further amended by adding at the end the following:

“(F) may, in the discretion of the Commission and subject to such conditions as the Commission may prescribe, allow professional or trade associations that are tax-exempt nonprofit organizations to send unsolicited advertisements to their members in furtherance of the association’s tax-exempt purpose that do not contain the notice required by paragraph (1)(C)(iii), except that the Commission may take action under this subparagraph only—

“(i) by regulation issued after public notice and opportunity for public comment; and

“(ii) if the Commission determines that such notice required by paragraph (1)(C)(iii) is not necessary to protect the ability of the members of such associations to stop such associations from sending any future unsolicited advertisements; and”.

(f) **AUTHORITY TO ESTABLISH TIME LIMIT ON ESTABLISHED BUSINESS RELATIONSHIP EXCEPTION.**—Section 227(b)(2) of the Communications Act of 1934 (47 U.S.C. 227(b)(2)), as amended by subsections (c), (d), and (e) of this section, is further amended by adding at the end the following:

“(G)(i) may, consistent with clause (ii), limit the duration of the existence of an established business relationship, however, before establishing any such limits, the Commission shall—

“(I) determine whether the existence of the exception under paragraph (1)(C) relating to an established business relationship has resulted in a significant number of complaints to the Commission regarding the sending of unsolicited advertisements to telephone facsimile machines;

“(II) determine whether a significant number of any such complaints involve unsolicited advertisements that were sent on the basis of an established business relationship that was longer in duration than the Commission believes is consistent with the reasonable expectations of consumers;

“(III) evaluate the costs to senders of demonstrating the existence of an established business relationship within a specified period of time and the benefits to recipients of establishing a limitation on such established business relationship; and

“(IV) determine whether with respect to small businesses, the costs would not be unduly burdensome; and

“(ii) may not commence a proceeding to determine whether to limit the duration of the existence of an established business relationship before the expiration of the 3-month period that begins on the date of the enactment of the Junk Fax Prevention Act of 2005.”

(g) **UNSOLICITED ADVERTISEMENT.**—Section 227(a)(5) of the Communications Act of 1934, as so redesignated by subsection (b)(1), is amended by inserting “, in writing or otherwise” before the period at the end.

47 USC 227 note.

(h) **REGULATIONS.**—Except as provided in section 227(b)(2)(G)(ii) of the Communications Act of 1934 (as added by subsection (f)), not later than 270 days after the date of enactment of this Act, the Federal Communications Commission shall issue regulations to implement the amendments made by this section.

SEC. 3. FCC ANNUAL REPORT REGARDING JUNK FAX ENFORCEMENT.

Section 227 of the Communications Act of 1934 (47 U.S.C. 227) is amended by adding at the end the following:

“(g) **JUNK FAX ENFORCEMENT REPORT.**—The Commission shall submit an annual report to Congress regarding the enforcement during the past year of the provisions of this section relating to sending of unsolicited advertisements to telephone facsimile machines, which report shall include—

“(1) the number of complaints received by the Commission during such year alleging that a consumer received an unsolicited advertisement via telephone facsimile machine in violation of the Commission’s rules;

“(2) the number of citations issued by the Commission pursuant to section 503 during the year to enforce any law, regulation, or policy relating to sending of unsolicited advertisements to telephone facsimile machines;

“(3) the number of notices of apparent liability issued by the Commission pursuant to section 503 during the year to enforce any law, regulation, or policy relating to sending of unsolicited advertisements to telephone facsimile machines;

“(4) for each notice referred to in paragraph (3)—

"(C) whether the recovery action resulted in collection of any amount, and if so, the amount collected."

SEC. 4. GAO STUDY OF JUNK FAX ENFORCEMENT.

(a) *IN GENERAL.*—The Comptroller General of the United States shall conduct a study regarding complaints received by the Federal Communications Commission concerning unsolicited advertisements sent to telephone facsimile machines, which shall determine—

(1) the mechanisms established by the Commission to receive, investigate, and respond to such complaints;

(2) the level of enforcement success achieved by the Commission regarding such complaints;

(3) whether complainants to the Commission are adequately informed by the Commission of the responses to their complaints; and

(4) whether additional enforcement measures are necessary to protect consumers, including recommendations regarding such additional enforcement measures.

(b) *ADDITIONAL ENFORCEMENT REMEDIES.*—In conducting the analysis and making the recommendations required under paragraph (7) of subsection (a), the Comptroller General shall specifically examine—

(1) the adequacy of existing statutory enforcement actions available to the Commission;

(2) the adequacy of existing statutory enforcement actions and remedies available to consumers;

(3) the impact of existing statutory enforcement remedies on senders of facsimiles;

(4) whether increasing the amount of financial penalties is warranted to achieve greater deterrent effect; and

(5) whether establishing penalties and enforcement actions for repeat violators or abusive violations similar to those established by section 4 of the CAN-SPAM Act of 2003 (15 U.S.C. 7703) would have a greater deterrent effect.

(c) *REPORT.*—Not later than 270 days after the date of the enactment of this Act, the Comptroller General shall submit a report on the results of the study under this section to Committee on Energy and Commerce of the House of Representatives and the Committee on Commerce, Science, and Transportation of the Senate.

The SPEAKER pro tempore. Pursuant to the rule, the gentleman from Michigan (Mr. UPTON) and the gentleman from Massachusetts (Mr. MARKEY) each will control 20 minutes.

The Chair recognizes the gentleman from Michigan (Mr. UPTON).

GENERAL LEAVE

Mr. UPTON. Mr. Speaker, I ask unanimous consent that all Members may have 5 legislative days within which to revise and extend their remarks and include extraneous material on H.R. 4600, as amended.

The SPEAKER pro tempore. Is there objection to the request of the gentleman from Michigan?

There was no objection.

Mr. UPTON. Mr. Speaker, I reserve the balance of my time.

Mr. MARKEY. Mr. Speaker, I yield myself such time as I may consume, and it is to make this point: That the majority worked very well with the minority on this issue. The gentleman from Michigan (Mr. DINGELL) and I and all the Members on our side want to thank the gentleman from Michigan (Mr. UPTON) and the gentleman from Texas (Mr. BARTON) for their cooperation on this legislation.

I was the principal House sponsor of the original junk fax bill back in 1991.

That bill worked quite well, but we need to update it, and this legislation will help to give the additional protections to American consumers so that they can protect themselves against the tsunami of unwanted junk faxes which go into their homes.

After all, what could be worse than to have something come into your home, consume paper in your fax machine that you have to pay for, and then not have an ability to be able to stop that person from sending any more junk faxes into your home?

That is what this bill will help to ensure does not occur in our country. The provisions in it, I think, are solid, they are sound, and they are the product of a bipartisan bill.

Mr. Speaker, I rise in support of this bill. This legislation reflects a compromise that was negotiated out between both Democratic and Republican Members over a number of weeks and I encourage Members to support this legislation today.

First, let me state that I was the principal House sponsor of the Telephone Consumer Protection Act (TCPA) of 1991, which contained the original junk fax prohibition. Congress endorsed my call in 1991 for a general prohibition against junk faxes because of the intrusive nature of that form of advertising. Junk faxes represent a form of advertising in which the ad is essentially paid for by the recipient. The recipient of a junk fax pays for the fax paper and printer costs, pays in the form of precious lost time as the machine is tied up, and also in the form of the clutter in which important faxes are lost in the midst of a pile of junk faxes.

I think it is important to emphasize that the bill we bring to the House floor today retains the general prohibition against sending junk faxes. In other words, sending an unsolicited facsimile advertisement is against the law. We are not changing the law or the policy with respect to this—sending a junk fax was illegal and remains illegal under this bill. Neither are we changing any of the statutory enforcement mechanisms available to the FCC or consumers in this bill.

The legislation we are proposing will address certain provisions affecting an exception to the general prohibition against sending junk faxes and will improve the bill in these areas. Since the FCC originally implemented the 1991 junk fax provisions of the TCPA, Commission regulations contained an exception for faxes that were sent because an "established business relationship" existed between the sender and the recipient. These regulations were in place and the ability to send junk faxes based upon the exception was permitted by the Commission for over a decade.

This concept of an "established business relationship" permitted a commercial entity to invoke its ability to prove such a relationship with a consumer in order to contact that consumer in spite of the general prohibitions of the law. The FCC has more recently determined that the term "established business relationship" was not specifically included in the provisions addressing junk faxes in the TCPA and therefore changed its regulations. The new rules require "written" permission from consumers and these new rules have been stayed from going into effect until January of 2005.

The legislation before us is designed to put specific language into the statute permitting an "established business relationship" exception to the general prohibition against junk faxes. Many businesses have complained that written permission is too onerous a regulatory requirement for many of the faxes that they stipulate are routinely sent in the ordinary course of business, presumably without complaints from the recipients of such faxes. The draft bill is responsive to these complaints.

We must recognize, however, that many small businesses and residential consumers find many of these unsolicited faxes, including those faxes sent because a valid claim of an "established business relationship" was being asserted in order to send them, to be a considerable irritant and strongly object to receiving them. The legislation, therefore, addresses additional issues, including putting into the statute an "opt-out" ability for consumers to object to receiving junk faxes, even when such faxes are sent to them based on an established business relationship. For the decade that the original FCC regulations were in place, many consumers simply were not aware of the FCC's established business relationship exception, nor did very many know they had an ability to stop these faxes or any clear way in which to effectuate such a request.

The bill the House is considering includes new provisions requiring an "opt-out" notice and policy that we will add to the statute. The bill requires junk faxes to include, on the first page, a clear and conspicuous notice to consumers that they have the right not to receive future junk faxes from the sender. Second, the notice must include a domestic contact telephone number an fax number for consumers to transmit a request not to receive future faxes. Third, the bill stipulates that consumers must be able to make such requests during normal business hours. Fourth, the bill requires the notice to conform with the Commission's technical and procedural standards for sending faxes under Section 227(d) of the law, which include the requirement to identify the entity sending the facsimile advertisement.

This is an important provision because one of the biggest complains from the FCC at the hearing, and with other law enforcement entities and aggrieved consumers, is that they have had difficulty legally identifying the source of many of the unsolicited faxes. In addition, there were some senders of junk faxes who evidently and falsely believed that simply because they were sending an unsolicited fax based upon their ability to prove they had a "established business relationship" with a consumer, and thus did not have to abide by the general prohibition against such faxes, that this also meant they did not have to abide by the other FCC and statutory technical rules. These statutory and regulatory rules include requirements that junk fax senders identify themselves in such faxes. Law enforcement entities and consumers need to be able to find the legal business name or widely recognized trade name of the entity sending a junk fax in violation of the rules in order to pursue enforcement actions.

Fifth, this bill makes it clear that a consumer can "opt-out" of receiving faxes to multiple machines, if they have more than one, rather than opting out solely for the particular machine that received the junk fax. Sixth, in this

legislation the Commission is tasked with exploring additional mechanisms by which a consumer might opt-out, such as in person or by e-mail or regular mail, and also requests that the Commission established cost-free ways by which consumers can opt-out. These notice and opt-out requirements all represent new provisions to the law for which existing enforcement remedies will apply.

This legislation also includes the ability for the FCC to limit the duration of an established business relationship notwithstanding the fact that the law would include an opt-out notice and ability which avails consumers of the right to opt-out of receiving faxes at any point in time. I believe this is an important concept and one which deals with the legitimate expectations of consumers. If a consumer buys something from a store, consumers might expect to hear from that store within a reasonable period of time under the notion that they have an established business relationship and the store was sending an unsolicited fax based upon that fact. Over time however, a consumer's expectation changes and there is a time after which the established business relationship can be said to have lapsed.

There are some who believe that no time limit is necessary, in light of the fact that we are now adding a clear way by which consumers may opt-out of receiving junk faxes at any time. There are others who believe that a time limit is necessary for consumer protection, and many of us have different views over what period of time is reasonable. While it is not the preferred resolution for any of us, the bill contains a new provision which tries to bridge the gap between our different perspectives on this issue. The legislation will permit the Commission to put in place a sunset of the established business relationship, after the FCC implements the new opt-out policy and it gets a track record on what is happening in the marketplace. In particular, the Commission will examine consumer complaints to the agency during this period with an analysis as to whether junk faxes from entities with whom consumers have an established business relationship constitute a significant number of complaints. If so, the Commission may establish a limit, between 5 and 7 years, for the duration of an established business relationship. If it does so, then after the limit, entities would not be able to send junk faxes because they can prove an established business relationship with a consumer. In other words, the relationship would end for purposes of the exception and the policy would revert back to the general prohibition against sending the junk fax for that consumer.

Finally, I think it is important to take a comprehensive look at overall enforcement of the junk fax law. I am concerned that some of the most egregious junk fax operations, the entities that broadcast such faxes to millions, often escape enforcement. They may be found guilty, cited by the FCC and sometimes fined—but often it appears as if they either ignore the fines, skip town, or live overseas. For these reasons the bill includes provisions that will give us an annual accounting of the FCC's enforcement activities as well as a GAO analysis of what additional enforcement tools may be necessary to provide sufficient deterrent, especially to the most egregious and abusive junk fax senders.

Again, I want to commend Chairman UPTON and Chairman BARTON for their work on this

bill, and in particular for their willingness and openness in working with me and Mr. DINGELL in crafting the compromises needed to achieve consensus. I encourage all the members to support it.

Mr. UPTON. Mr. Speaker, I yield myself such time as I may consume.

Mr. Speaker, today we are considering the Junk Fax Prevention Act of 2004, bipartisan legislation which I introduced along with the gentleman from Massachusetts (Mr. MARKEY), the gentleman from Texas (Mr. BARTON) and the gentleman from Michigan (Mr. DINGELL). I want to thank those Members for their hard work and bipartisan cooperation.

In 1991, Congress passed the Telephone Consumer Protection Act, which included landmark legislation that protected consumers from receiving unwanted and unsolicited commercial faxes. For over 10 years, the FCC had interpreted that law to provide businesses with an exception to the general ban when they faxed commercial or advertising material to an existing business customer.

Then, in 2003, the FCC made a major change in their interpretation of the law. Under the new FCC rules, every business, every single one, small, large, home-based, every association, every nonprofit organization, every charity, would be required to obtain prior written approval from each individual before it sent a commercial fax.

□ 1900

The logistical and financial costs of the new FCC rules, particularly to small business and nonprofit associations, would be enormous.

For instance, the survey of the U.S. Chamber of Commerce suggested that the cost to the average small business would be at least \$5,000 in the first year and more than \$3,000 each year thereafter. The survey further indicated that it would take, on average, more than 27 hours of staff time to obtain the initial written consent from their customers, and an additional 20 hours each year to keep those forms current. A recent survey by the National Association of Wholesalers-Distributors revealed that its member companies expected to pay an average of \$22,500 just to obtain the consent forms. With our economy in the fragile stages of an economic recovery, I would much rather see those dollars going towards production and job creation.

Given the dramatic impact which the new rules would have, last August, just before the new rules were to go into effect, the gentleman from Louisiana (Mr. TAUZIN), the then chairman of the Committee on Energy and Commerce, and I wrote the FCC and requested that the FCC delay the effective date of the new rules. Thankfully, the FCC did. In fact, they stayed the effective date until January of 2005.

Moreover, while the FCC currently has the new rules under reconsideration, I think it is the wisest course for Congress to step in and fix the law to

resolve any lingering statutory interpretation problems which led to the FCC's new rules, and that is why we are here today.

Let me start by stating what the Junk Fax Prevention Act of 2004 would not do. The bill does not overturn the ban on the faxing of unsolicited advertisements. That has been outlawed since the passage of the Telephone Consumer Protection Act of 1991, and this bill does nothing to change that.

This bill does not protect the senders of those annoying, unsolicited faxed advertisements which so many of us get from companies with whom we have never done business, often sent to us randomly by blast fax, and do not properly identify themselves in the fax transmission.

Rather, the bill with clearly restate the established business relationship exemption to allow businesses, associations, and charities to send commercial faxes to their customers and members without first receiving written permission. Additionally and importantly, the bill would establish new opt-out safeguards to provide additional protections for fax recipients. Under the bill, senders of faxes must alert recipients clearly and conspicuously on the first page, of their right to opt-out of future faxes, and senders must abide by those requests. This is a level of protection that consumers never had under the FCC rules. Finally, the bill sets out the FCC reporting requirements so that Congress can monitor the FCC's enforcement activity.

The Junk Fax Prevention Act is commonsense, regulatory relief; and time is of the essence for Congress to pass it, since many businesses will very soon need to begin making arrangements to be in compliance with the new rules by January of 2005.

I want to thank my friends, the gentleman from Massachusetts (Mr. MARKEY), the gentleman from Texas (Mr. BARTON), and the gentleman from Michigan (Mr. DINGELL), for their sincere bipartisan cooperation on the bill. I also want to thank the staff on both sides of the aisle, Kelly Cole, Howard Waltzman, Pete Filon, Colin Crowell, Will Carly, and certainly Will Nordwind for all of their superb efforts.

I urge my colleagues to support this measure. I look forward to working with my colleagues on the other side of the Capitol to ensure that we get this must-pass legislation to the President's desk as expeditiously as possible this year.

Mr. DINGELL. Mr. Speaker, I rise in support of H.R. 4600, the Junk Fax Prevention Act of 2004. The bill strikes a proper balance between protecting consumers from unwanted junk faxes and permitting legitimate business communications, and I would commend Chairman BARTON and UPTON, and Ranking Member MARKEY for their bipartisan work.

H.R. 4600 is necessary because the Federal Communications Commission (FCC), as part of its Do-Not-Call order last year, reversed its existing business relationship (EBR) policy regarding junk faxes. Starting in January 2005, permission to receive junk faxes

must be in writing and include the recipient's signature.

This rule will have a perverse effect on legitimate business communications. For example, under the Commission's new policy, if I would like my travel agent to send me a description of various vacation packages, I must first deliver to my agent a signed waiver requesting the fax. Likewise, my favorite restaurant would have to obtain a similar waiver in order to fax me its updated menu. Not surprisingly, commercial enterprises, especially small businesses and trade associations, are justifiably concerned about the impact of the FCC's new junk fax rules.

H.R. 4600 takes the corrective step of codifying a modified version of the FCC's current 12-year-old junk fax EBR policy that is set to end this year. To provide further protection to consumers, however, that policy will be changed to provide consumers with the right to opt out from receiving such faxes from a particular sender. Further, consumers must be provided clear and conspicuous notice of their new opt-out right. Additional protections for consumers include enabling recipients to opt out using a cost-free mechanism and giving the FCC the authority to sunset the EBR.

In an effort to focus on enforcement against those who illegally send junk faxes, the legislation requires the Commission to report to the Congress each year on the number of junk fax complaints it has received and on the enforcement actions taken against those who violate the agency's rules. This report should assist the commission in maintaining proper vigilance on those who fail to respect consumer privacy. Moreover, the bill requires the Government Accountability Office to study the junk fax issue and make recommendations to the Committee on additional enforcement measures that can be taken to protect consumers from unwanted junk faxes.

Mr. Speaker, consumers are fed up with the unwanted and intrusive junk faxes that clog up their fax machines. H.R. 4600 will help protect consumers from receiving these faxes while ensuring that businesses can continue to use the fax machine to communicate with their customers. I urge my colleagues to support this bill.

Mr. UPTON. Mr. Speaker, I have no further requests for time, and I yield back the balance of my time.

The SPEAKER pro tempore (Mr. HENSARLING). The question is on the motion offered by the gentleman from Michigan (Mr. UPTON) that the House suspend the rules and pass the bill, H.R. 4600, as amended.

The question was taken; and (two-thirds having voted in favor thereof) the rules were suspended and the bill, as amended, was passed.

A motion to reconsider was laid on the table.

MINOR USE AND MINOR SPECIES ANIMAL HEALTH ACT OF 2004

Mr. PICKERING. Mr. Speaker, I move to suspend the rules and pass the Senate bill (S. 741) to amend the Federal Food, Drug, and Cosmetic Act with regard to new animal drugs, and for other purposes.

The Clerk read as follows:

S. 741

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

TITLE I—MINOR USE AND MINOR SPECIES HEALTH

SECTION 101. SHORT TITLE.

This title may be cited as the "Minor Use and Minor Species Animal Health Act of 2004".

SEC. 102. MINOR USE AND MINOR SPECIES ANIMAL HEALTH.

(a) FINDINGS.—Congress makes the following findings:

(1) There is a severe shortage of approved new animal drugs for use in minor species.

(2) There is a severe shortage of approved new animal drugs for treating animal diseases and conditions that occur infrequently or in limited geographic areas.

(3) Because of the small market shares, low-profit margins involved, and capital investment required, it is generally not economically feasible for new animal drug applicants to pursue approvals for these species, diseases, and conditions.

(4) Because the populations for which such new animal drugs are intended may be small and conditions of animal management may vary widely, it is often difficult to design and conduct studies to establish drug safety and effectiveness under traditional new animal drug approval processes.

(5) It is in the public interest and in the interest of animal welfare to provide for special procedures to allow the lawful use and marketing of certain new animal drugs for minor species and minor uses that take into account these special circumstances and that ensure that such drugs do not endanger animal or public health.

(6) Exclusive marketing rights for clinical testing expenses have helped encourage the development of "orphan" drugs for human use, and comparable incentives should encourage the development of new animal drugs for minor species and minor uses.

(b) AMENDMENTS TO THE FEDERAL FOOD, DRUG, AND COSMETIC ACT.—

(1) DEFINITIONS.—Section 201 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321) is amended by adding at the end the following:

"(nn) The term 'major species' means cattle, horses, swine, chickens, turkeys, dogs, and cats, except that the Secretary may add species to this definition by regulation.

"(oo) The term 'minor species' means animals other than humans that are not major species.

"(pp) The term 'minor use' means the intended use of a drug in a major species for an indication that occurs infrequently and in only a small number of animals or in limited geographical areas and in only a small number of animals annually."

(2) THREE-YEAR EXCLUSIVITY FOR MINOR USE AND MINOR SPECIES APPROVALS.—Section 512(c)(2)(F) (ii), (iii), and (v) of the Federal Food, Drug, and Cosmetic Act is amended by striking "(other than bioequivalence or residue studies)" and inserting "(other than bioequivalence studies or residue depletion studies, except residue depletion studies for minor uses or minor species)" every place it appears.

(3) SCOPE OF REVIEW FOR MINOR USE AND MINOR SPECIES APPLICATIONS.—Section 512(d) of the Federal Food, Drug, and Cosmetic Act is amended by adding at the end the following new paragraph:

"(5) In reviewing an application that proposes a change to add an intended use for a minor use or a minor species to an approved new animal drug application, the Secretary shall reevaluate only the relevant information in the approved application to deter-

mine whether the application for the minor use or minor species can be approved. A decision to approve the application for the minor use or minor species is not, implicitly or explicitly, a reaffirmation of the approval of the original application."

(4) MINOR USE AND MINOR SPECIES NEW ANIMAL DRUGS.—Chapter V of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351 et seq.) is amended by adding at the end the following:

"Subchapter F—New Animal Drugs for Minor Use and Minor Species

"SEC. 571. CONDITIONAL APPROVAL OF NEW ANIMAL DRUGS FOR MINOR USE AND MINOR SPECIES.

"(a)(1) Except as provided in paragraph (3) of this section, any person may file with the Secretary an application for conditional approval of a new animal drug intended for a minor use or a minor species. Such an application may not be a supplement to an application approved under section 512. Such application must comply in all respects with the provisions of section 512 of this Act except sections 512(a)(4), 512(b)(2), 512(c)(1), 512(c)(2), 512(c)(3), 512(d)(1), 512(e), 512(h), and 512(n) unless otherwise stated in this section, and any additional provisions of this section. New animal drugs are subject to application of the same safety standards that would be applied to such drugs under section 512(d) (including, for antimicrobial new animal drugs, with respect to antimicrobial resistance).

"(2) The applicant shall submit to the Secretary as part of an application for the conditional approval of a new animal drug—

"(A) all information necessary to meet the requirements of section 512(b)(1) except section 512(b)(1)(A);

"(B) full reports of investigations which have been made to show whether or not such drug is safe under section 512(d) (including, for an antimicrobial new animal drug, with respect to antimicrobial resistance) and there is a reasonable expectation of effectiveness for use;

"(C) data for establishing a conditional dose;

"(D) projections of expected need and the justification for that expectation based on the best information available;

"(E) information regarding the quantity of drug expected to be distributed on an annual basis to meet the expected need; and

"(F) a commitment that the applicant will conduct additional investigations to meet the requirements for the full demonstration of effectiveness under section 512(d)(1)(E) within 5 years.

"(3) A person may not file an application under paragraph (1) if—

"(A) the application seeks conditional approval of a new animal drug that is contained in, or is a product of, a transgenic animal,

"(B) the person has previously filed an application for conditional approval under paragraph (1) for the same drug in the same dosage form for the same intended use whether or not subsequently conditionally approved by the Secretary under subsection (b), or

"(C) the person obtained the application, or data or other information contained therein, directly or indirectly from the person who filed for conditional approval under paragraph (1) for the same drug in the same dosage form for the same intended use whether or not subsequently conditionally approved by the Secretary under subsection (b).

"(b) Within 180 days after the filing of an application pursuant to subsection (a), or such additional period as may be agreed upon by the Secretary and the applicant, the Secretary shall either—