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**To the Honorable**
**Representative Robin L. Kelly**
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https://www.congress.gov/bill/117th-congress/house-bill/5313/cosponsors

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H.R.5313 - Reese's Law 117th Congress (2021-2022)
Sponsor: Rep. Kelly, Robin L. [D-IL-2] (Introduced 09/21/2021)
Committees: House - Energy and Commerce
Committee Reports: H. Rept. 117-440
Latest Action: 08/16/2022 Became Public Law No: 117-171.

**Reese's law: adverse unintended consequences; seeking remediation; battery type 312 zinc air.**

**Part 1: Statement of problem, solution: remediation at packaging (PREVIOUSLY SENT).**
**Part 2: Existing Federal Regs, relevant or even in conflict (THIS LETTER).**

**Briefly: THIS child-proofing is also extreme adult-proofing against the elderly, the hearing aid population, my group, battery type 312, zinc-air, commonly used for hearing aids, I am age 80.**

I previously sent to your office, my extreme unhappiness with Reese's law, in that its child-proofing is also adult proofing - against the elderly/ senior population, my group – who are disproportionately hearing-aid users, who will be adversely impacted/ harmed by this packaging. I propose solutions, at (i) packaging, and (ii) at the law/ regulatory level, since I predict inevitable senior injury from trying to open these packages - 'foreseeable injury' - the basis of product liability litigation. Product liability is a prominent part of consumer safety.

I seek to mitigate and modify the law as written; and submit that committee Counsel has interpretive authority for these mitigation proposals. If that pathway is NOT available, I still seek to record my concerns, narrowly, of Reese, re hearing-aid batteries packaging. Thank you for your continuing advocacy for consumer safety

IN THIS LETTER I present extant language and perhaps wisdom, from the mass of words at CFR Code of Federal Regulations.

Please note: I am not your geographic electoral constituent. Rather, I write to you as you are sponsor of this law, with unintended and severe adverse national outcomes, as I develop below. As you are the law sponsor I submit that you have a national constituency for legislative actions with national impact.

I present two issues here addressed in CFR, **(1) Zinc Air hearing aid batteries,** and **(2) senior testing**.

Re this latter, the letters after my name are social science; I have done NDA (New Drug Applications) to FDA, for two pharmaceutical companies. Those submissions include how users use products.

Sampling is the critical issue for testing. The sampling here is not useful, even counter-useful, ie misleading. The numbers are too small for statistical reliability (also called 'significance') and they are the wrong age groups, again I am age 80, my group is not sampled. Also the subjects are restricted to healthy, contra the aged population, which has age-related disabilities which are central to this testing, These concerns are all developed below or were addressed in my previous letter.

**(1) Zinc air batteries.**

These are the batteries I use, let us take a product description from Amazon my supplier:

Size 312 PR41 1.45V **Zinc Air** Hearing Aid Batteries Brown Tab (60 Batteries)
Visit the Hear Clear Store

==>> Note **Zinc air,** emphasis supplied.

Now to CFR on zinc air batteries, and Reese's concern, ingestion:

https://www.ecfr.gov/current/title-16/chapter-II/subchapter-B/part-1263

§ 1263.1 Scope, purpose, effective date, and exemption.

> **(d)** ***Batteries that do not present an ingestion hazard.*** Button cell or coin batteries that the Commission has determined do not present an ingestion hazard are not subject to this part. **These are: zinc-air button cell or coin batteries. (emphasis supplied)**

This sounds pretty definitive, perhaps you would reconsider Reese, narrowly.

Before turning to **(2) Senior testing as described at CFR**, which is lengthy, I offer, that hearing aid technology HAS moved past these batteries, and now sells hearing aids that may be dropped into a charger, just as we have many rechargeable devices, often with charging wires, HOWEVER, such a device runs to the $250 range, vs batteries at pennies each, and so are One More Expensive Thing to have to carry and lose and worry about....

What this means, in practice and prediction, is that as **non-ingestible batteries per CFR**, just above, now become inaccessible because of adult-proof packaging, folks will feel pressure to abandon these old battery-powered hearing aids, and upgrade to battery-free rechargeables. Since hearing aids start at $2000 per ear, or $4000 per pair, I submit and predict substantial pain and outrage, and who will be the target of this unhappiness? the battery manufacturers? who now include a pointer to Reese's law, and, per minimal internet keystrokes, point to your office and sponsorship? I suspect so and predict so.

And one more prefatory note, before presenting the extended CFR senior testing protocols.

I am in the process of upgrading my hearing aids, which is always traumatic, major expense and unknown benefit, the new devices come from the manufacturer with the new-packaging batteries; the

audiologist says, she “does not know how to open this new packaging”. She is a hearing aid professional, I emphasize. And so what of us aging poor slobs who have survived long enough to be undone by child-proofing? I submit, **not without a fight**.

(2) Now to CFR, and to us geezers and antiques, oops seniors. Please note, this is lengthy. I have slightly reformatted for readability,

https://www.ecfr.gov/current/title-16/chapter-II/subchapter-E/part-1700/section-1700.20

§ 1700.20 Testing procedure for special packaging.
(a) Test protocols —
(3) Senior-adult panel —

https://www.ecfr.gov/current/title-16/part-1700/section-1700.20#p-1700.20(a)(3)
16 CFR 1700.20(a)(3)

> ***Test subjects.*** Use a group of 100 senior adults. Not more than 24% of the senior adults tested shall be obtained from or tested at any one site. Each group of senior adults shall be randomly selected as to age, subject to the limitations set forth below.
>
> Twenty-five percent of the participants shall be 50-54 years of age, [N=25]
>
> 25% of participants shall be 55-59 years of age, [N=25]
>
> and 50% of the participants shall be 60-70 years old. [N=50, say half 60-65 and half 65-70]

Comment: I don't see any 80 year-olds, and if we take seniority as Social Security eligibility ie age 65, and parse that the 60-70 group is half above 65 and half below 65, then in our 100 person sample TWENTY FIVE are above 65 and ZERO above 70!! Per Wiki, the honorable Representative is age 68, that is, barely represented in this sample.

**In Sum? Bah humbug re protecting seniors who elsewhere in law are a protected category.**

Accordingly, perhaps you will reconsider your overly-broad legislation language.

Continuing, CFR is 'downstream' from legislation, not binding, of course, but as decisional language often states, regarding non-binding precedent, Courts “may be guided by the persuasiveness of the reasoning of these ancillary discussions”. I urge so.

Continuing:

> Seventy percent of the participants of ages 50-59 and ages 60-70 shall be female (17 or 18 females shall be apportioned to the 50-54 year age group). No individual tester shall administer the test to more than 35% of the senior adults tested. **The adults selected should have no obvious or overt physical or mental disability. (emphasis supplied)**

**Continuing - no overt disability.** BUT we codgers and coots and decrepitated persons, with age-related: visual-, motor, and grip-strength declines - **MUST** also be included, else we have an artificial sample, so? Lawyers start your engines. Perhaps instead of a Black Box (FDA terminology of danger) language against child access we will have a warning against antiques using these items,. Your call.

If I am sarcastic, I am imposed upon. Thus 'legislative feedback.' I missed the comment period.

Continuing, contra the biases and inadequate, even counter-adequate, sampling, the remainder of the senior testing protocol is length and quite detailed. I append for completeness (with some repetition).

https://www.ecfr.gov/current/title-16/part-1700/section-1700.20#p-1700.20(a)(3)

(repeated)

> ***Test subjects.*** Use a group of 100 senior adults. Not more than 24% of the senior adults tested shall be obtained from or tested at any one site. Each group of senior adults shall be randomly selected as to age, subject to the limitations set forth below. Twenty-five percent of the participants shall be 50-54 years of age, 25% of participants shall be 55-59 years of age, and 50% of the participants shall be 60-70 years old. **Seventy percent of the participants of ages 50-59 and ages 60-70 shall be female (17 or 18 females shall be apportioned to the 50-54 year age group**). No individual tester shall administer the test to more than 35% of the senior adults tested. The adults selected should have no obvious or overt physical or mental disability. (**Gender emphasis supplied**)

(new)

> ***(ii) Screening procedures.*** Participants who are unable to open the packaging being tested in the first 5-minute time period, are given a screening test. The screening tests for this purpose shall use two packages with conventional (not child-resistant (CR) or "special") closures. One closure shall be a plastic snap closure and the other a CT plastic closure. Each closure shall have a diameter of 28 mm±18%, and the CT closures shall have been resecured 72 hours before testing at 10 inch-pounds of torque. The containers for both the snap- and CT-type closures shall be round plastic containers, in sizes of 2 ounce± 1⁄2 ounce for the CT-type closure and 8 drams±4 drams for the snap-type closure. **Persons who cannot open and close both of the screening packages in 1-minute screening tests shall not be counted as participants in the senior-adult panel**. (emphasis supplied).

**COMMENT EXACTLY WRONG as explained above and below.**

> (iii) ***SAUE.*** The senior adult use effectiveness (SAUE) is the percentage of adults who both opened the package in the first (5-minute) test period and opened and (if appropriate) properly resecured the package in the 1-minute test period.
>
> ***(iv) Test procedures.*** The senior adults shall be tested individually, rather than in groups of two or more. The senior adults shall receive only such printed instructions on how to open and properly secure the special packaging as will appear on or accompany the package as it is delivered to the consumer. The senior-adult panel is tested according to the procedure incorporated in the following senior-adult panel test instructions:

# Test Instructions for Senior Test

The following test instructions are used for all senior tests. If non-reclosable packages are being tested, the commands to close the package are eliminated.

**1. No adult with a permanent or temporary illness, injury, or disability that would interfere with his/her effective participation shall be included in the test. (Exactly wrong. Emphasis supplied.)**

2. Each adult shall read and sign a consent form prior to participating. Any appropriate language from the consent form may be used to recruit potential participants. The form shall include the basic elements of informed consent as defined in 16 CFR 1028.116. Examples of the forms used

by the Commission staff for testing are shown at § 1700.20(d). Before beginning the test, the tester shall say, “PLEASE READ AND SIGN THIS CONSENT FORM.” If an adult cannot read the consent form for any reason (forgot glasses, illiterate, etc.), he/she shall not participate in the test.

3. Each adult shall participate individually and not in the presence of other participants or onlookers.

4. The tests shall be conducted in well-lighted and distraction-free areas. **(This is also wrong, batteries are replaced in cars and on the subway and in hectic circumstances**.) (Emphasis supplied.)

5. Records shall be filled in before or after the test, so that the tester's full attention is on the participant during the test period. Recording the test times to open and resecure the package are the only exceptions.

6. To begin the first 5-minute test period, the tester says, “I AM GOING TO ASK YOU TO OPEN AND PROPERLY CLOSE THESE TWO IDENTICAL PACKAGES ACCORDING TO THE INSTRUCTIONS FOUND ON THE CAP.” (Specify other instruction locations if appropriate.)

7. The first package is handed to the participant by the tester, who says, “PLEASE OPEN THIS PACKAGE ACCORDING TO THE INSTRUCTIONS ON THE CAP.” (Specify other instruction locations if appropriate.) If the package contains product, the tester shall say, “PLEASE EMPTY THE (PILLS, TABLETS, CONTENTS, etc.) INTO THIS CONTAINER.” After the participant opens the package, the tester says, “PLEASE CLOSE THE PACKAGE PROPERLY, ACCORDING TO THE INSTRUCTIONS ON THE CAP.” (Specify other instruction locations if appropriate)

8. Participants are allowed up to 5 minutes to read the instructions and open and close the package. The tester uses a stopwatch(s) or other timing device to time the opening and resecuring times. The elapsed times in seconds to open the package and to close the package are recorded on the data sheet as two separate times.

9. After 5 minutes, or when the participant has opened and closed the package, whichever comes first, the tester shall take all test materials from the participant. The participant may remove and replace the closure more than once if the participant initiates these actions. If the participant does not open the package and stops trying to open it before the end of the 5-minute period, the tester shall say, “ARE YOU FINISHED WITH THAT PACKAGE, OR WOULD YOU LIKE TO TRY AGAIN?” If the participant indicates that he/she is finished or cannot open the package and does not wish to continue trying, skip to Instruction 13.

10. To begin the second test period, the tester shall give the participant another, but identical, package and say, “THIS IS AN IDENTICAL PACKAGE. PLEASE OPEN IT ACCORDING TO THE INSTRUCTIONS ON THE CAP.” (Specify other instruction locations if appropriate.) If the package contains product, the tester shall say, “PLEASE EMPTY THE (PILLS, TABLETS, CONTENTS, etc.) INTO THIS CONTAINER.” After the participant opens the package, the tester says, “PLEASE CLOSE THE PACKAGE PROPERLY, ACCORDING TO THE INSTRUCTIONS ON THE CAP.” (Specify other instruction locations if appropriate.)

11. The participants are allowed up to 1 minute (60 full seconds) to open and close the package. The elapsed times in seconds to open and to close the package are recorded on the data sheet as two separate times. The time that elapses between the opening of the package and the end of the instruction to close the package is not counted as part of the 1-minute test time.

12. After the 1-minute test, or when the participant has opened and finished closing the package, whichever comes first, the tester shall take all the test materials from the participant. The participant shall not be allowed to handle the package again. If the participant does not open the package and stops trying to open it before the end of the 1-minute period, the tester shall say, "ARE YOU FINISHED WITH THAT PACKAGE, OR WOULD YOU LIKE TO TRY AGAIN?" If the participant indicates that he/she is finished or cannot open the package and does not wish to continue trying, this shall be counted as a failure of the 1-minute test.

13. Participants who do not open the package in the first 5-minute test period are asked to open and close two non-child-resistant screening packages. The participants are given a 1-minute test period for each package. The tester shall give the participant a package and say, "PLEASE OPEN AND PROPERLY CLOSE THIS PACKAGE." The tester records the time for opening and closing, or 61 seconds, whichever is less, on the data sheet. The tester then gives the participant the second package and says, "PLEASE OPEN AND PROPERLY CLOSE THIS PACKAGE." The time to open and resecure, or 61 seconds, whichever is less, shall be recorded on the data sheet.

14. Participants who cannot open and resecure both of the non-child-resistant screening packages are not counted as part of the 100-seniors panel. Additional participants are selected and tested.

15. No adult may participate in more than two tests per sitting. If a person participates in two tests, the packages tested shall not be the same ASTM type of package.

16. If more adults in a sex or age group are tested than are necessary to determine SAUE, the last person(s) tested shall be eliminated from that group.

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**Quite exacting, but withal, futile b/c of the sampling failure and environmental control – well lighted. distraction free - when in practice the daily environment is out of control, certainly not laboratory immaculate.**

Thank you for your continuing advocacy for consumer safety.

[Redacted]

NYC November 18, 2024